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FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

SERVICE AND REGULATORY ANNOUNCEMENTS

Food, Drug, and Cosmetic No. 1

Revision 3

FEDERAL FOOD, DRUG, AND COSMETIC ACT AND GENERAL REGULATIONS FOR ITS ENFORCEMENT

INTRODUCTION

This publication contains an unofficial print of the Federal Food, Drug, and Cosmetic Act, as amended, and general regulations, as amended, for its administration. The third revision incorporates all changes made in the Act and general regulations since the printing of the second revision in July 1946. The section numbers of the regulations printed herein have been revised to comply with the changes in the Code of Federal Regulations announced in the Federal Register of November 27, 1948 (13 F. R. 6969). Footnote references are made to certain regulations authorized by the Act that are not reprinted in this republication. Single copies of such regulations may be obtained by application to the Food and Drug Administration, Federal Security Agency, Washington 25, D. C.

Oscar R. Ewing

Federal Security Administrator

February 7, 1949.

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PUBLIC—NO. 717—SEVENTY-FIFTH CONGRESS, CHAPTER 675, THIRD SESSION, S. 5

AN ACT

To prohibit the movement in interstate commerce of adulterated and misbranded food, drugs, devices, and cosmetics, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

CHAPTER I—SHORT TITLE

SECTION 1. This Act may be cited as the Federal Food, Drug, and Cosmetic Act.

General Regulation. [§ 1.1] (a) The provisions of regulations promulgated under the Act with respect to the doing of any act shall be applicable also to the causing of such act to be done.

(b) The definitions and interpretations of terms contained in section 201 of the Act shall be applicable also to such terms when used in regulations promulgated under the Act.

CHAPTER II—DEFINITIONS

SEC. 201. For the purposes of this Act—

(a) The term "Territory" means any Territory or possession of the United States, including the District of Columbia and excluding the Canal Zone.

(b) The term "interstate commerce" means (1) commerce between any State or Territory and any place outside thereof, and (2) commerce within the District of Columbia or within any other Territory not organized with a legislative body.

(c) The term "Agency" means the Federal Security Agency.

(d) The term "Administrator" means the Federal Security Administrator.

(e) The term "person" includes individual, partnership, corporation, and association.

(f) The term "food" means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.

(g) The term "drug" means (1) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (3) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (4) articles intended for use as a component of any articles specified in clause (1), (2), or (3); but does not include devices or their components, parts, or accessories.

(h) The term "device" (except when used in paragraph (n) of this section and in sections 301 (i), 403 (f), 502 (c), and 602 (c)) means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or (2) to affect the structure or any function of the body of man or other animals.

(i) The term "cosmetic" means (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap.

(j) The term "official compendium" means the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, official National Formulary, or any supplement to any of them.

(k) The term "label" means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this Act that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper.

(l) The term "immediate container" does not include package liners.

(m) The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

Regulation. [§ 1.2] Labeling includes all written, printed, or graphic matter accompanying an article at any time while such article is in interstate commerce or held for sale after shipment or delivery in interstate commerce.

[SEC. 201. For the purposes of this Act—]

(n) If an article is alleged to be misbranded because the labeling is misleading, then in determining whether the labeling is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling relates under the conditions of use prescribed in the labeling thereof or under such conditions of use as are customary or usual.

Regulation. [§ 1.3] The existence of a difference of opinion, among experts qualified by scientific training and experience, as to the truth of a representation made or suggested in the labeling is a fact (among other facts) the failure to reveal which may render the labeling misleading, if there is a material weight of opinion contrary to such representation.

[SEC. 201. For the purposes of this Act—]

(o) The representation of a drug, in its labeling, as an antiseptic shall be considered to be a representation that it is a germicide, except in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or such other use as involves prolonged contact with the body.

(p) The term "new drug" means—

(1) Any drug the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of drugs, as safe for use under the conditions prescribed, recommended, or suggested in the labeling thereof, except that such a drug not so recognized shall not be deemed to be a "new drug" if at any time prior to the enactment of this Act it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or

(2) Any drug the composition of which is such that such drug, as a result of investigations to determine its safety for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

Regulation. [§ 1.108] Newness of a drug may arise by reason (among other reasons) of:

(a) The newness for drug use of any substance which composes such drug, in whole or in part, whether it be an active substance or a menstruum, excipient, carrier, coating, or other component;

(b) The newness for drug use of a combination of two or more substances, none of which is a new drug;

(c) The newness for drug use of the proportion of a substance in a combination, even though such combination containing such substance in other proportion is not a new drug;

(d) The newness of use of such drug in diagnosing, curing, mitigating, treating, or preventing a disease, or to affect a structure or function of the body, even though such drug is not a new drug when used in another disease or to affect another structure or function of the body; or

(e) The newness of a dosage, or method or duration of administration or application, or other condition of use prescribed, recommended, or suggested in the labeling of such drug, even though such drug when used in other dosage, or other method or duration of administration or application, or different condition, is not a new drug.

CHAPTER III—PROHIBITED ACTS AND PENALTIES

PROHIBITED ACTS

SEC. 301. The following acts and the causing thereof are hereby prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.

(b) The adulteration or misbranding of any food, drug, device, or cosmetic in interstate commerce.

(c) The receipt in interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

(d) The introduction or delivery for introduction into interstate commerce of any article in violation of section 404 or 505.

(e) The refusal to permit access to or copying of any record as required by section 703.

(f) The refusal to permit entry or inspection as authorized by section 704.

(g) The manufacture within any Territory of any food, drug, device, or cosmetic that is adulterated or misbranded.

(h) The giving of a guaranty or undertaking referred to in section 303 (c) (2), which guaranty or undertaking is false, except by a person who relied upon a guaranty or undertaking to the same effect signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the food, drug, device, or cosmetic; or the giving of a guaranty or undertaking referred to in section 303 (c) (3), which guaranty or undertaking is false.

Regulation. [§ 1.4] In case of the giving of a guaranty or undertaking referred to in section 303 (c) (2) or (3) of the Act, each person signing such guaranty or undertaking shall be considered to have given it.

[SEC. 301. The following acts and the causing thereof are hereby prohibited:]

(i) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp, tag, label, or other identification device authorized or required by regulations promulgated under the provisions of section 404, 406 (b), 504, 506, 507, or 604.

(j) The using by any person to his own advantage, or revealing, other than to the Administrator or officers or employees of the Agency, or to the courts when relevant in any judicial proceeding under this Act, any information acquired under authority of section 404, 505, 506, 507, or 704 concerning any method or process which as a trade secret is entitled to protection.

(k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded.

(l) The using, on the labeling of any drug or in any advertising relating to such drug, of any representation or suggestion that an application with respect to such drug is effective under section 505, or that such drug complies with the provisions of such section.

INJUNCTION PROCEEDINGS

SEC. 302. (a) The district courts of the United States and the United States courts of the Territories shall have jurisdiction, for cause shown, and subject to the provisions of section 17 (relating to notice to opposite party) of the Act entitled "An Act to supplement existing laws against unlawful restraints and monopolies, and for other purposes," approved October 15, 1914, as amended (U. S. C., 1934 ed., title 28, sec. 381), to restrain violations of section 301, except paragraphs (e), (f), (h), (i), and (j).

(b) In case of violation of an injunction or restraining order issued under this section, which also constitutes a violation of this Act, trial shall be by the court, or, upon demand of the accused, by a jury. Such trial shall be conducted in accordance with the practice and procedure applicable in the case of proceedings subject to the provisions of section 22 of such Act of October 15, 1914, as amended (U. S. C., 1934 ed., title 28, sec. 387).

PENALTIES

Sec. 303. (a) Any person who violates any of the provisions of section 301 shall be guilty of a misdemeanor and shall on conviction thereof be subject to imprisonment for not more than one year, or a fine of not more than $1,000, or both such imprisonment and fine; but if the violation is committed after a conviction of such person under this section has become final such person shall be subject to imprisonment for not more than three years, or a fine of not more than $10,000, or both such imprisonment and fine.

(b) Notwithstanding the provisions of subsection (a) of this section, in case of a violation of any of the provisions of section 301, with intent to defraud or mislead, the penalty shall be imprisonment for not more than three years, or a fine of not more than $10,000, or both such imprisonment and fine.

(c) No person shall be subject to the penalties of subsection (a) of this section, (1) for having received in interstate commerce any article and delivered it or proffered delivery of it, if such delivery or proffer was made in good faith, unless he refuses to furnish on request of an officer or employee duly designated by the Administrator the name and address of the person from whom he purchased or received such article and copies of all documents, if any there be, pertaining to the delivery of the article to him; or (2) for having violated section 301 (a) or (d), if he establishes a guaranty or undertaking signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the article, to the effect, in case of an alleged violation of section 301 (a), that such article is not adulterated or misbranded, within the meaning of this Act, designating this Act, or to the effect, in case of an alleged violation of section 301 (d), that such article is not an article which may not, under the provisions of section 404 or 505, be introduced into interstate commerce; or (3) for having violated section 301 (a), where the violation exists because the article is adulterated by reason of containing a coal-tar color not from a batch certified in accordance with regulations promulgated by the Administrator under this Act, if such person establishes a guaranty or undertaking signed by, and containing the name and address of, the manufacturer of the coal-tar color, to the effect that such color was from a batch certified in accordance with the applicable regulations promulgated by the Administrator under this Act.

Regulation. [§ 1.5] (a) A guaranty or undertaking referred to in section 303 (c) (2) of the Act may be:

(1) limited to a specific shipment or other delivery of an article, in which case it may be a part of or attached to the invoice or bill of sale covering such shipment or delivery, or

(2) general and continuing, in which case, in its application to any shipment or other delivery of an article, it shall be considered to have been given at the date such article was shipped or delivered by the person who gives the guaranty or undertaking.

(b) The following are suggested forms of guaranty or undertaking under section 303 (c) (2) of the Act:

(1) Limited Form for use on invoice or bill of sale.

(Name of person giving the guaranty or undertaking) hereby guarantees that no article listed herein is adulterated or misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act, or is an article which may not, under the provisions of section 404 or 505 of the Act, be introduced into interstate commerce.

(Signature and post-office address of person giving the guaranty or undertaking.)

(2) General and Continuing Form.

The article comprising each shipment or other delivery hereafter made by (name of person giving the guaranty or undertaking) to, or on the order of (name and post-office address of person to whom the guaranty or undertaking is given) is hereby guaranteed, as of the date of such shipment or delivery, to be, on such date, not adulterated or misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act, and not an article which may not, under the provisions of section 404 or 505 of the Act, be introduced into interstate commerce.

(Signature and post-office address of person giving the guaranty or undertaking.)

(c) The application of a guaranty or undertaking referred to in section 303 (c) (2) of the Act to any shipment or other delivery of an article shall expire when such article, after shipment or delivery by the person who gave such guaranty or undertaking, becomes adulterated or misbranded within the meaning of the Act, or becomes an article which may not, under the provisions of section 404 or 505 of the Act, be introduced into interstate commerce.

(d) A guaranty or undertaking referred to in section 303 (c) (3) of the Act shall state that the shipment or other delivery of coal-tar color covered thereby was manufactured by a signer thereof. It may be a part of or attached to the invoice or bill of sale covering such color. If such shipment or delivery is from a foreign manufacturer, such guaranty or undertaking shall be signed by such manufacturer and by an agent of such manufacturer who resides in the United States.

(e) The following are suggested forms of guaranty or undertaking under section 303 (c) (3) of the Act:

(1) For domestic manufacturers.

(Name of manufacturer) hereby guarantees that all coal-tar colors listed herein were manufactured by him, and are from batches certified in accordance with the applicable regulations promulgated under the Federal Food, Drug, and Cosmetic Act.

(Signature and post-office address of manufacturer.)

(2) For foreign manufacturers.

(Name of manufacturer and agent) hereby severally guarantee that all coal-tar colors listed herein were manufactured by (name of manufacturer), and are from batches certified in accordance with the applicable regulations promulgated under the Federal Food, Drug, and Cosmetic Act.

(Signature and post-office address of manufacturer.)

(Signature and post-office address of agent.)

(f) For the purpose of a guaranty or undertaking under section 303 (c) (3) of the Act the manufacturer of a shipment or other delivery of a coal-tar color is the person who packaged such color.

(g) A guaranty or undertaking, if signed by two or more persons, shall state that such persons severally guarantee the article to which it applies.

(h) No representation or suggestion that an article is guaranteed under the Act shall be made in labeling.

SEIZURE

SEC. 304. (a) Any article of food, drug, device, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce or while held for sale (whether or not the first sale) after shipment in interstate commerce, or which may not, under the provisions of section 404 or 505, be introduced into interstate commerce, shall be liable to be proceeded against while in interstate commerce, or at anytime thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found: *Provided, however,* That no libel for condemnation shall be instituted under this Act, for any alleged misbranding if there is pending in any court a libel for condemnation proceeding under this Act based upon the same alleged misbranding, and not more than one such proceeding shall be instituted if no such proceeding is so pending, except that such limitations shall not apply (1) when such misbranding has been the basis of a prior judgment in favor of the United States, in a criminal, injunction, or libel for condemnation proceeding under this Act, or (2) when the Administrator has probable cause to believe from facts found, without hearing, by him or any officer or employee of the Agency that the misbranded article is dangerous to health, or that the labeling of the misbranded article is fraudulent, or would be in a material respect misleading to the injury or damage of the purchaser or consumer. In any case where the number of libel for condemnation proceedings is limited as above provided the proceeding pending or instituted shall, on application of the claimant, seasonably made, be removed for trial to any district agreed upon by stipulation between the parties, or, in case of failure to so stipulate within a reasonable time, the claimant may apply to the court of the district in which the seizure has been made, and such court (after giving the United States attorney for such district reasonable notice and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business to which the case shall be removed for trial.

(b) The article shall be liable to seizure by process pursuant to the libel, and the procedure in cases under this section shall conform, as nearly as may be, to the procedure in admiralty; except that on demand of either party any issue of fact joined in any such case shall be tried by jury. When libel for condemnation proceedings under this section, involving the same claimant and the same issues of adulteration or misbranding, are pending in two or more jurisdictions, such pending proceedings, upon application of the claimant seasonably made to the court of one such jurisdiction, shall be consolidated for trial by order of such court, and tried in (1) any district selected by the claimant where one of such proceedings is pending; or (2) a district agreed upon by stipulation between the parties. If no order for consolidation is so made within a reasonable time, the claimant may apply to the court of one such jurisdiction, and such court (after giving the United States attorney for such district reasonable notice and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the

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claimant's principal place of business, in which all such pending proceedings shall be consolidated for trial and tried. Such order of consolidation shall not apply so as to require the removal of any case the date for trial of which has been fixed. The court granting such order shall give prompt notification thereof to the other courts having jurisdiction of the cases covered thereby.

(c) The court at any time after seizure up to a reasonable time before trial shall by order allow any party to a condemnation proceeding, his attorney or agent, to obtain a representative sample of the article seized, and as regards fresh fruits or fresh vegetables, a true copy of the analysis on which the proceeding is based and the identifying marks or numbers, if any, of the packages from which the samples analyzed were obtained.

(d) Any food, drug, device, or cosmetic condemned under this section shall, after entry of the decree, be disposed of by destruction or sale as the court may, in accordance with the provisions of this section, direct and the proceeds thereof, if sold, less the legal costs and charges, shall be paid into the Treasury of the United States; but such article shall not be sold under such decree contrary to the provisions of this Act or the laws of the jurisdiction in which sold: *Provided*, That after entry of the decree and upon the payment of the costs of such proceedings and the execution of a good and sufficient bond conditioned that such article shall not be sold or disposed of contrary to the provisions of this Act or the laws of any State or Territory in which sold, the court may by order direct that such article be delivered to the owner thereof to be destroyed or brought into compliance with the provisions of this Act under the supervision of an officer or employee duly designated by the Administrator, and the expenses of such supervision shall be paid by the person obtaining release of the article under bond. Any article condemned by reason of its being an article which may not, under section 404 or 505, be introduced into interstate commerce, shall be disposed of by destruction.

(e) When a decree of condemnation is entered against the article, court costs and fees, and storage and other proper expenses, shall be awarded against the person, if any, intervening as claimant of the article.

(f) In the case of removal for trial of any case as provided by subsection (a) or (b)—

(1) The clerk of the court from which removal is made shall promptly transmit to the court in which the case is to be tried all records in the case necessary in order that such court may exercise jurisdiction.

(2) The court to which such case was removed shall have the powers and be subject to the duties, for purposes of such case, which the court from which removal was made would have had, or to which such court would have been subject, if such case had not been removed.

HEARING BEFORE REPORT OF CRIMINAL VIOLATION

SEC. 305. Before any violation of this Act is reported by the Administrator to any United States attorney for institution of a criminal proceeding, the person against whom such proceeding is con-

templated shall be given appropriate notice and an opportunity to present his views, either orally or in writing, with regard to such contemplated proceeding.

Regulation. [§1.6] (a) Presentation of views under section 305 of the Act shall be private and informal. The views presented shall be confined to matters relevant to the contemplated proceeding. Such views may be presented by letter or in person by the person to whom the notice was given, or by his representative. In case such person holds a guaranty or undertaking referred to in section 303 (c) (2) or (3) of the Act applicable to the article on which such notice was based, such guaranty or undertaking, or a verified copy thereof, shall be made a part of such presentation of views.

(b) Upon request, seasonably made, by the person to whom a notice appointing a time and place for the presentation of views under section 305 of the Act has been given, or by his representative, such time or place, or both such time and place, may be changed if the request states reasonable grounds therefor. Such request shall be addressed to the office of the Food and Drug Administration which issued the notice.

REPORT OF MINOR VIOLATIONS

SEC. 306. Nothing in this Act shall be construed as requiring the Administrator to report for prosecution, or for the institution of libel or injunction proceedings, minor violations of this Act whenever he believes that the public interest will be adequately served by a suitable written notice or warning.

PROCEEDINGS IN NAME OF UNITED STATES; PROVISION AS TO SUBPENAS

SEC. 307. All such proceedings for the enforcement, or to restrain violations, of this Act shall be by and in the name of the United States. Notwithstanding the provisions of section 876 of the Revised Statutes, subpenas for witnesses who are required to attend a court of the United States, in any district, may run into any other district in any such proceeding.

CHAPTER IV—FOOD

DEFINITIONS AND STANDARDS FOR FOOD

SEC. 401. Whenever in the judgment of the Administrator such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations[1] fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity, a reasonable standard of quality, and/or reasonable standards of fill of container: *Provided*, That no definition and standard of identity and no standard of quality shall be established for fresh or dried fruits, fresh or dried vegetables, or butter, except that definitions and standards of identity may be established for avocadoes, cantaloupes, citrus fruits, and melons. In prescribing any standard of fill of container, the Administrator shall give due consideration to the natural shrinkage in storage and in transit of fresh natural food and to need for the necessary packing and protective material. In the prescribing of any standard of quality for

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any canned fruit or canned vegetable, consideration shall be given and due allowance made for the differing characteristics of the several varieties of such fruit or vegetable. In prescribing a definition and standard of identity for any food or class of food in which optional ingredients are permitted, the Administrator shall, for the purpose of promoting honesty and fair dealing in the interest of consumers, designate the optional ingredients which shall be named on the label. Any definition and standard of identity prescribed by the Administrator for avocadoes, cantaloupes, citrus fruits, or melons shall relate only to maturity and to the effects of freezing.

ADULTERATED FOOD

SEC. 402. A food shall be deemed to be adulterated—

(a) (1) It it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or (2) if it bears or contains any added poisonous or added deleterious substance which is unsafe within the meaning of section 406; or (3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or (4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or (5) if it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter; or (6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health.

(b) (1) If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or (2) if any substance has been substituted wholly or in part therefor; or (3) if damage or inferiority has been concealed in any manner; or (4) if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.

(c) If it bears or contains a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by section 406: *Provided*, That this paragraph shall not apply to citrus fruit bearing or containing a coal-tar color if application for listing of such color has been made under this Act and such application has not been acted on by the Administrator, if such color was commonly used prior to the enactment of this Act for the purpose of coloring citrus fruit.

(d) If it is confectionery, and it bears or contains any alcohol or nonnutritive article or substance except harmless coloring, harmless flavoring, harmless resinous glaze not in excess of four-tenths of 1 per centum, natural gum, and pectin: *Provided*, That this paragraph shall not apply to any confectionery by reason of its containing less than one-half of 1 per centum by volume of alcohol derived solely from the use of flavoring extracts, or to any chewing gum by reason of its containing harmless nonnutritive masticatory substances.

MISBRANDED FOOD

SEC. 403. A food shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular.

Regulation. [§ 1.7] (a) Among representations in the labeling of a food which render such food misbranded is a false or misleading representation with respect to another food or a drug, device, or cosmetic.

(b) The labeling of a food which contains two or more ingredients may be misleading by reason (among other reasons) of the designation of such food in such labeling by a name which includes or suggests the name of one or more but not all such ingredients, even though the names of all such ingredients are stated elsewhere in the labeling.

[SEC. 403. A food shall be deemed to be misbranded—]

(b) If it is offered for sale under the name of another food.

(c) If it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word "imitation" and, immediately thereafter, the name of the food imitated.

(d) If its container is so made, formed, or filled as to be misleading.

(e) If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: *Provided*, That under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Administrator.

Regulation. [§ 1.8] (a) Where a food is not manufactured by the person whose name appears on the label, the name shall be qualified by a phrase which reveals the connection such person has with such food, such as "Manufactured for and Packed by ----------," "Distributed by ----------," or other similar phrase which expresses the facts.

(b) The statement of the place of business shall include the street address, if any, of such place, unless such street address is shown in a current city directory or telephone directory.

(c) If a person manufactures, packs, or distributes a food at a place other than his principal place of business, the label may state the principal place of business in lieu of the actual place where each package of such food was manufactured or packed or is to be distributed, if such statement is not misleading in any particular.

(d) The requirement that the label shall contain the name and place of business of the manufacturer, packer, or distributor shall not be considered to relieve any food from the requirement that its label shall not be misleading in any particular.

(e) (1) The statement of the quantity of the contents shall reveal the quantity of food in the package, exclusive of wrappers and other material packed with such food.

(2) The statement shall be expressed in the terms of weight, measure, numerical count, or a combination of numerical count and weight or measure, which are generally used by consumers to express quantity of such food and which give accurate information as to the quantity thereof. But if no general consumer usage in expressing accurate information as to the quantity of such food exists, the statement shall be in terms of liquid measure if the food is liquid, or in terms of weight if the food is solid, semisolid, viscous, or a mixture of solid and liquid; except that such statement may be in terms of dry measure if the food is a fresh fruit, fresh vegetable, or other dry commodity.

(f) (1) A statement of weight shall be in terms of the avoirdupois pound and ounce. A statement of liquid measure shall be in terms of the United States gallon of 231 cubic inches and quart, pint, and fluid ounce subdivisions thereof, and, except in case of frozen food which is so consumed, shall express the volume at 68° Fahrenheit (20° Centigrade). A statement of dry measure shall be in terms of the United States bushel of 2150.42 cubic inches and peck, dry quart, and dry pint subdivisions thereof; or in terms of the United States standard barrel and its subdivisions of third, half, and three-quarters barrel. However, in the case of an export shipment, the statement may be in terms of a system of weight or measure in common use in the country to which such shipment is exported.

(2) A statement of weight or measure in the terms specified in subparagraph (1) of this paragraph may be supplemented by a statement in terms of the metric system of weight or measure.

(3) Unless an unqualified statement of numerical count gives accurate information as to the quantity of food in the package, it shall be supplemented by such statement of weight, measure, or size of the individual units of the food as will give such information.

(g) Statements shall contain only such fractions as are generally used in expressing the quantity of the food. A common fraction shall be reduced to its lowest terms; a decimal fraction shall not be carried out to more than two places.

(h) (1) If the quantity of food in the package equals or exceeds the smallest unit of weight or measure which is specified in paragraph (f) of this section, and which is applicable to such food under the provisions of paragraph (e) (2) of this section, the statement shall express the number of the largest of such units contained in the package (for example, the statement on the label of a package which contains one quart of food shall be "1 quart", and not "2 pints" or "32 fluid ounces"), unless the statement is made in accordance with the provisions of subparagraph (2) of this paragraph. Where such number is a whole number and a fraction, there may be substituted for the fraction its equivalent in smaller units, if any smaller is specified in such paragraph (f) (for examples, 1¾ quarts may be expressed as "1 quart 1½ pints" or "1 quart 1 pint 8 fluid ounces"; 1¼ pounds may be expressed as "1 pound 4 ounces"). The stated number of any unit which is smaller than the largest unit (specified in such paragraph (f)) contained in the package shall not equal or exceed the number of such smaller units in the next larger unit so specified (for examples, instead of "1 quart 16 fluid ounces" the statement shall be "1½ quarts" or "1 quart 1 pint"; instead of "24 ounces" the statement shall be "1½ pounds" or "1 pound 8 ounces").

(2) In the case of a food with respect to which there exists an established custom of stating the quantity of the contents as a fraction of a unit, which unit is larger than the quantity contained in the package, or as units smaller than the largest unit contained therein, the statement may be made in accordance with such custom if it is informative to consumers.

(i) The statement shall express the minimum quantity, or the average quantity, of the contents of the packages. If the statement is not so qualified as to show definitely that the quantity expressed is the minimum quantity, the statement shall be considered to express the average quantity.

(j) Where the statement expresses the minimum quantity, no variation below the stated minimum shall be permitted except variations below the stated weight or measure caused by ordinary and customary exposure, after the food is introduced into interstate commerce, to conditions which normally occur in good distribution practice and which unavoidably result in decreased weight or measure. Variations above the stated minimum shall not be unreasonably large.

(k) Where the statement does not express the minimum quantity:

(1) variations from the stated weight or measure shall be permitted when caused by ordinary and customary exposure, after the food is introduced into interstate commerce, to conditions which normally occur in good distribution practice and which unavoidably result in change of weight or measure;

(2) variations from the stated weight, measure, or numerical count shall be permitted when caused by unavoidable deviations in weighing, measuring, or counting individual packages which occur in good packing practice.

But under subparagraph (2) of this paragraph variations shall not be permitted to such extent that the average of the quantities in the packages comprising a shipment or other delivery of the food is below the quantity stated, and no unreasonable shortage in any package shall be permitted, even though overages in other packages in the same shipment or delivery compensate for such shortage.

(l) The extent of variations from the stated quantity of the contents permissible under paragraphs (j) and (k) of this section in the case of each shipment or other delivery shall be determined by the facts in such case.

(m) A food shall be exempt from compliance with the requirements of clause (2) of section 403 (e) of the Act if:

(1) The quantity of the contents, as expressed in terms applicable to such food under the provisions of paragraph (e) (2) of this section, is less than one-half ounce avoirdupois, or less than one-half fluid ounce, or (in case the units of the food can be easily counted without opening the package) less than six units; or

(2) The statement of the quantity of the contents of the package, together with all other words, statements, and information required by or under authority of the Act to appear on the label, cannot, because of insufficient label space, be so placed on the label as to comply with the requirements of section 403 (f) of the Act and regulations promulgated thereunder.

[Sec. 403. A food shall be deemed to be misbranded—]

(f) If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

Regulation. [§ 1.9] (a) A word, statement, or other information required by or under authority of the Act to appear on the label may lack that prominence and conspicuousness required by section 403 (f) of the Act by reason (among other reasons) of:

(1) The failure of such word, statement, or information to appear on the part or panel of the label which is presented or displayed under customary conditions of purchase;

(2) The failure of such word, statement, or information to appear on two or more parts or panels of the label, each of which has sufficient space therefor, and each of which is so designed as to render it likely to be, under customary conditions of purchase, the part or panel displayed;

(3) The failure of the label to extend over the area of the container or package available for such extension, so as to provide sufficient label space for the prominent placing of such word, statement, or information;

(4) Insufficiency of label space (for the prominent placing of such word, statement, or information) resulting from the use of label space for any word, statement, design, or device which is not required by or under authority of the Act to appear on the label;

(5) Insufficiency of label space (for the prominent placing of such word, statement, or information) resulting from the use of label space to give materially greater conspicuousness to any other word, statement, or information, or to any design or device; or

(6) Smallness or style of type in which such word, statement, or information appears, insufficient background contrast, obscuring designs or vignettes, or crowding with other written, printed, or graphic matter.

(b) No exemption depending on insufficiency of label space, as prescribed in regulations promulgated under section 403 (e) or (i) of the Act, shall apply if such insufficiency is caused by:

(1) The use of label space for any word, statement, design, or device which is not required by or under authority of the Act to appear on the label;

(2) The use of label space, to give greater conspicuousness to any word, statement, or other information than is required by section 403 (f) of the Act; or

(3) The use of label space for any representation in a foreign language.

(c) (1) All words, statements, and other information required by or under authority of the Act to appear on the label or labeling shall appear thereon in the English language.

(2) If the label contains any representation in a foreign language, all words, statements, and other information required by or under authority of the Act to appear on the label shall appear thereon in the foreign language.

(3) If the labeling contains any representation in a foreign language, all words, statements, and other information required by or under authority of the Act to appear on the label or labeling shall appear on the labeling in the foreign language.

[SEC. 403. A food shall be deemed to be misbranded—]

(g) If it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations as provided by section 401, unless (1) it conforms to such definition and standard, and (2) its label bears the name of the food specified in the definition and standard, and, insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food.

Regulation. [§ 1.14] In the following conditions, among others, a food does not conform to the definition and standard of identity therefor:

(a) If it contains an ingredient for which no provision is made in such definition and standard;

(b) If it fails to contain any one or more ingredients required by such definition and standard;

(c) If the quantity of any ingredient or component fails to conform to the limitation, if any, prescribed therefor by such definition and standard.

[SEC. 403. A food shall be deemed misbranded—]

(h) If it purports to be or is represented as—

(1) a food for which a standard of quality has been prescribed by regulations as provided by section 401, and its quality falls below such standard, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard; or

(2) a food for which a standard or standards of fill of container have been prescribed by regulations as provided by section 401, and it falls below the standard of fill of container applicable thereto, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard.

(i) If it is not subject to the provisions of paragraph (g) of this section unless its label bears (1) the common or usual name of the food, if any there be, and (2) in case it is fabricated from two or more ingredients, the common or usual name of each such ingredient; except that spices, flavorings, and colorings, other than those sold as such, may be designated as spices, flavorings, and colorings without naming each: *Provided*, That, to the extent that compliance with the requirements of clause (2) of this paragraph is impracticable, or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the Administrator.

Regulation. [§1.10] (a) The name of an ingredient (except a spice, flavoring, or coloring which is an ingredient of a food other than one sold as a spice, flavoring, or coloring), required by section 403 (i) (2) of the Act to be borne on the label of a food, shall be a specific name and not a collective name. But if an ingredient (which itself contains two or more ingredients) conforms to a definition and standard of identity prescribed by regulations under section 401 of the Act, such ingredient may be designated on the label of such food by the name specified in the definition and standard, supplemented, in case such regulations require the naming of optional ingredients present in such ingredient, by a statement showing the optional ingredients which are present in such ingredient.

(b) No ingredient shall be designated on the label as a spice, flavoring, or coloring unless it is a spice, flavoring, or coloring, as the case may be, within the meaning of such term as commonly understood by consumers. The term "coloring" shall not include any bleaching substance.

(c) An ingredient which is both a spice and a coloring, or both a flavoring and a coloring, shall be designated as spice and coloring, or flavoring and coloring, as the case may be, unless such ingredient is designated by its specific name.

(d) A label may be misleading by reason (among other reasons) of:

(1) The order in which the names of ingredients appear thereon, or the relative prominence otherwise given such names; or

(2) Its failure to reveal the proportion of, or other fact with respect to, an ingredient, when such proportion or other fact is material in the light of the representation that such ingredient was used in fabricating the food.

(e) (1) A food shall be exempt from the requirements of clause (2) of section 403 (i) of the Act if all words, statements, and other information required by or under authority of the Act to appear on the label of such food, cannot, because of insufficient label space, be so placed on the label as to comply with the requirements of section 403 (f) of the Act and regulations promulgated thereunder. But such exemption shall be on the condition that, if the omission from the label of the statement of the quantity of the contents affords sufficient space to state legibly thereon all the information required by such clause (2), such statement of the quantity of the contents shall be omitted as authorized by §1.9 (m) (2), and the information required by such clause (2) shall be so stated as prominently as practicable even though the statement is not of such conspicuousness as to render it likely to be read by the ordinary individual under customary conditions of purchase.

(2) In the case of an assortment of different items of food, when variations in the items which make up different packages packed from such assortment normally occur in good packing practice, and when such variations result in variations in the ingredients in different packages, such food shall be exempt from compliance with the requirements of clause (2) of section 403 (i) of the Act with respect to any ingredient which is not common to all packages. But such exemption shall be on the condition that the label shall bear, in conjunction with the names of such ingredients as are common to all packages, a statement in terms which are as informative as practicable and which are not misleading, indicating that other ingredients may be present.

[Sec. 403. A food shall be deemed to be misbranded—]

(j) If it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as the Administrator determines to be, and by regulations [2] prescribes as, necessary in order fully to inform purchasers as to its value for such uses.

Regulation. [§ 1.11] (a) The term "special dietary uses", as applied to food for man, means particular (as distinguished from general) uses of food, as follows:

(1) Uses for supplying particular dietary needs which exist by reason of a physical, physiological, pathological or other condition, including but not limited to the conditions of disease, convalescence, pregnancy, lactation, allergic hypersensitivity to food, underweight, and overweight;

[2] 21 CFR, Cum. Supp., 125.1 *et seq.*; 6 F. R. 5925.

(2) Uses for supplying particular dietary needs which exist by reason of age, including but not limited to the ages of infancy and childhood;

(3) Uses for supplementing or fortifying the ordinary or usual diet with any vitamin, mineral, or other dietary property. Any such particular use of a food is a special dietary use, regardless of whether such food also purports to be or is represented for general use.

(b) No provision of any regulation under section 403 (j) of the Act shall be construed as exempting any food from any other provision of the Act or regulations thereunder, including sections 403 (a) and (g) and, when applicable, the provisions of Chapter V.

(k) If it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears labeling stating that fact: *Provided*, That to the extent that compliance with the requirements of this paragraph is impracticable, exemptions shall be established by regulations promulgated by the Administrator. The provisions of this paragraph and paragraphs (g) and (i) with respect to artificial coloring shall not apply in the case of butter, cheese, or ice cream.

Regulation. [§1.12] (a) (1) The term "artificial flavoring" means a flavoring containing any sapid or aromatic constituent, which constituent was manufactured by a process of synthesis or other similar artifice.

(2) The term "artificial coloring" means a coloring containing any dye or pigment, which dye or pigment was manufactured by a process of synthesis or other similar artifice, or a coloring which was manufactured by extracting a natural dye or natural pigment from a plant or other material in which such dye or pigment was naturally produced.

(3) The term "chemical preservative" means any chemical which, when added to food, tends to prevent or retard deterioration thereof; but does not include common salt, sugars, vinegars, spices or oils extracted from spices, or substances added to food by direct exposure thereof to wood smoke.

(b) A food which is subject to the requirements of section 403 (k) of the Act shall bear labeling, even though such food is not in package form.

(c) A statement of artificial flavoring, artificial coloring, or chemical preservative shall be placed on the food, or on its container or wrapper, or on any two or all of these, as may be necessary to render such statement likely to be read by the ordinary individual under customary conditions of purchase and use of such food.

(d) A food shall be exempt from compliance with the requirements of section 403 (k) of the Act if it is not in package form and the units thereof are so small that a statement of artificial flavoring, artificial coloring, or chemical preservative, as the case may be, cannot be placed on such units with such conspicuousness as to render it likely to be read by the ordinary individual under customary conditions of purchase and use.

EMERGENCY PERMIT CONTROL

SEC. 404. (a) Whenever the Administrator finds after investigation that the distribution in interstate commerce of any class of food may, by reason of contamination with micro-organisms during the manufacture, processing, or packing thereof in any locality, be injurious to health, and that such injurious nature cannot be adequately determined after such articles have entered interstate commerce, he then, and in such case only, shall promulgate regulations providing for the issuance, to manufacturers, processors, or packers of such class of food in such locality, of permits to which shall be attached such conditions governing the manufacture, processing, or packing of such class of food, for such temporary period of time, as may be necessary to protect the public health; and after the effective

date of such regulations, and during such temporary period, no person shall introduce or deliver for introduction into interstate commerce any such food manufactured, processed, or packed by any such manufacturer, processor, or packer unless such manufacturer, processor, or packer holds a permit issued by the Administrator as provided by such regulations.

(b) The Administrator is authorized to suspend immediately upon notice any permit issued under authority of this section if it is found that any of the conditions of the permit have been violated. The holder of a permit so suspended shall be privileged at any time to apply for the reinstatement of such permit, and the Administrator shall, immediately after prompt hearing and an inspection of the establishment, reinstate such permit if it is found that adequate measures have been taken to comply with and maintain the conditions of the permit, as originally issued or as amended.

(c) Any officer or employee duly designated by the Administrator shall have access to any factory or establishment, the operator of which holds a permit from the Administrator, for the purpose of ascertaining whether or not the conditions of the permit are being complied with, and denial of access for such inspection shall be ground for suspension of the permit until such access is freely given by the operator.

REGULATIONS MAKING EXEMPTIONS

SEC. 405. The Administrator shall promulgate regulations exempting from any labeling requirement of this Act (1) small open containers of fresh fruits and fresh vegetables and (2) food which is, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such food is not adulterated or misbranded under the provisions of this Act upon removal from such processing, labeling, or repacking establishment.

Regulation. [§ 1.13] (a) (1) An open container is a container of rigid or semirigid construction, which is not closed by lid, wrapper, or otherwise.

(2) An open container of a fresh fruit or fresh vegetable, the quantity of contents of which is not more than one dry quart, shall be exempt from the labeling requirements of paragraphs (e), (g) (2) (with respect to the name of the food specified in the definition and standard), and (i) (1) of section 403 of the Act; but such exemption shall be on the condition that if two or more such containers are enclosed in a crate or other shipping package, such crate or package shall bear labeling showing the number of such containers enclosed therein and the quantity of the contents of each.

(b) Except as provided by paragraphs (c) and (d) of this section, a shipment or other delivery of a food which is, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantity at an establishment other than that where originally processed or packed, shall be exempt, during the time of introduction into and movement in interstate commerce and the time of holding in such establishment, from compliance with the labeling requirements of section 403 (c), (e), (g), (h), (i), (j) and (k) of the Act if:

(1) The person who introduced such shipment or delivery into interstate commerce is the operator of the establishment where such food is to be processed, labeled, or repacked; or

(2) In case such person is not such operator, such shipment or delivery is made to such establishment under a written agreement, signed by and containing the post-office addresses of such person and such operator, and containing such specifications for the processing, labeling, or repacking, as the case may be, of such food in such establishment as will insure, if such specifications are followed, that such food will not be adulterated or misbranded within the meaning of the Act upon completion of such processing, labeling, or repacking. Such person and such operator shall each keep a copy of such agreement until all such shipment or delivery has been removed from such establishment, and shall make such copies available for inspection at any reasonable hour to any officer or employee of the Agency who requests them.

(c) An exemption of a shipment or other delivery of a food under paragraph (b) (1) of this section shall, at the beginning of the act of removing such shipment or delivery, or any part thereof, from such establishment, become void *ab initio* if the food comprising such shipment, delivery, or part is adulterated or misbranded within the meaning of the Act when so removed.

(d) An exemption of a shipment or other delivery of a food under paragraph (b) (2) of this section shall become void *ab initio* with respect to the person who introduced such shipment or delivery into interstate commerce upon refusal by such person to make available for inspection a copy of the agreement, as required by such paragraph.

(e) An exemption of a shipment or other delivery of a food under paragraph (b) (2) of this section shall expire:

(1) At the beginning of the act of removing such shipment or delivery, or any part thereof, from such establishment if the food comprising such shipment, delivery, or part is adulterated or misbranded within the meaning of the Act when so removed; or

(2) Upon refusal by the operator of the establishment where such food is to be processed, labeled, or repacked, to make available for inspection a copy of the agreement, as required by such paragraph.

TOLERANCES FOR POISONOUS INGREDIENTS IN FOOD AND CERTIFICATION OF COAL-TAR COLORS FOR FOOD

SEC. 406. (a) Any poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice shall be deemed to be unsafe for purposes of the application of clause (2) of section 402 (a); but when such substance is so required or cannot be so avoided, the Administrator shall promulgate regulations [3] limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health, and any quantity exceeding the limits so fixed shall also be deemed to be unsafe for purposes of the application of clause (2) of section 402 (a). While such a regulation is in effect limiting the quantity of any such substance in the case of any food, such food shall not, by reason of bearing or containing any added amount of such substance, be considered to be adulterated within the meaning of clause (1) of section 402 (a). In determining the quantity of such added substance to be tolerated in or on different articles of food the Administrator shall take into account the extent to which the use of such substance is required or cannot be avoided in the production of each such article, and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances.

[3] 21 CFR, 1944 Supp., 120.1 *et seq.*; 9 F. R. 11836.

(b) The Administrator shall promulgate regulations providing for the listing of coal-tar colors [4] which are harmless and suitable for use in food and for the certification of batches of such colors, with or without harmless diluents.

CHAPTER V—DRUGS AND DEVICES

ADULTERATED DRUGS AND DEVICES

SEC. 501. A drug or device shall be deemed to be adulterated—

(a) (1) If it consists in whole or in part of any filthy, putrid, or decomposed substance; or (2) if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or (3) if it is a drug and its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (4) if it is a drug and it bears or contains, for purposes of coloring only, a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by section 504.

(b) If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium. Such determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in such compendium, except that whenever tests or methods of assay have not been prescribed in such compendium, or such tests or methods of assay as are prescribed are, in the judgment of the Administrator, insufficient for the making of such determination, the Administrator shall bring such fact to the attention of the appropriate body charged with the revision of such compendium, and if such body fails within a reasonable time to prescribe test or methods of assay which, in the judgment of the Administrator, are sufficient for purposes of this paragraph, then the Administrator shall promulgate regulations prescribing appropriate tests or methods of assay in accordance with which such determination as to strength, quality, or purity shall be made. No drug defined in an official compendium shall be deemed to be adulterated under this paragraph because it differs from the standard of strength, quality, or purity therefor set forth in such compendium, if its difference in strength, quality, or purity from such standard is plainly stated on its label. Whenever a drug is recognized in both the United States Pharmacopoeia and the Homoeopathic Pharmacopoeia of the United States it shall be subject to the requirements of the United States Pharmacopoeia unless it is labeled and offered for sale as a homoeopathic drug, in which which case it shall be subject to the provisions of the Homoeopathic Pharmacopoeia of the United States and not to those of the United States Pharmacopoeia.

Regulation. [§ 1.100] (a) The name by which a drug is designated shall be clearly distinguishing and differentiating from any name recognized in an official compendium unless such drug complies in identity with the identity prescribed in an official compendium under such recognized name.

[4] Service and Regulatory Announcements, Food, Drug, and Cosmetic No. 3.

(b) The term "drug defined in an official compendium" means a drug having the identity prescribed for a drug in an official compendium.

(c) A statement that a drug defined in an official compendium differs in strength, quality, or purity from the standard of strength, quality, or purity set forth for such drug in an official compendium shall show all the respects in which such drug so differs, and the extent of each such difference.

[Sec. 501. A drug or device shall be deemed to be adulterated—]

(c) If it is not subject to the provisions of paragraph (b) of this section and its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess.

(d) If it is a drug and any substance has been (1) mixed or packed therewith so as to reduce its quality or strength or (2) substituted wholly or in part therefor.

MISBRANDED DRUGS AND DEVICES

Sec. 502. A drug or device shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular.

Regulation. [§ 1.101] (a) Among representations in the labeling of a drug or device which render such drug or device misbranded is a false or misleading representation with respect to another drug or device or a food or cosmetic.

(b) The labeling of a drug which contains two or more ingredients may be misleading by reason (among other reasons) of the designation of such drug in such labeling by a name which includes or suggests the name of one or more but not all such ingredients, even though the names of all such ingredients are stated elsewhere in the labeling.

[Sec. 502. A drug or device shall be deemed to be misbranded—]

(b) If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: *Provided*, That under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Administrator.

Regulation. [§ 1.102] (a) If a drug or device is not manufactured by the person whose name appears on the label, the name shall be qualified by a phrase which reveals the connection such person has with such drug or device, such as "Manufactured for and Packed by ----------," "Distributed by ----------," or other similar phrase which expresses the facts.

(b) The statement of the place of business shall include the street address, if any, of such place, unless such street address is shown in a current city directory or telephone directory.

(c) Where a person manufactures, packs, or distributes a drug or device at a place other than his principal place of business, the label may state the principal place of business in lieu of the actual place where each package of such drug or device was manufactured or packed or is to be distributed, if such statement is not misleading in any particular.

(d) The requirement that the label shall contain the name and place of business of the manufacturer, packer, or distributor shall not be considered to relieve any drug or device from the requirement that its label shall not be misleading in any particular.

(e) (1) The statement of the quantity of the contents of a package of a drug shall reveal the quantity of such drug in the package, exclusive of wrappers and other material packed with such drug.

(2) The statement shall be expressed in the terms of weight, measure, numerical count, or a combination of numerical count and weight or measure, which are generally used by consumers and users of such drug to express quantity thereof and which give accurate information as to such quantity. But if no general usage in expressing accurate

information as to the quantity of such drug exists among consumers and users thereof, the statement of the quantity of a drug which is not in tablet, capsule, ampul, or other unit form shall be in terms of weight if the drug is solid, semisolid, or viscous, or in terms of measure if the drug is liquid; the statement of the quantity of a drug which is in such unit form shall be in terms of the numerical count of such units, supplemented, when necessary to give accurate information as to the quantity of such drug in the package, by such statement (in such terms, manner, and form as are not misleading) of the weight or measure of such units, or of the quantity of each active ingredient in each such unit, as will give such information.

(3) The statement of the quantity of a device shall be expressed in terms of numerical count.

(f) A statement of weight shall be in terms of the avoirdupois pound, ounce, and grain, or of the kilogram, gram, and milligram. A statement of liquid measure shall be in terms of the United States gallon of 231 cubic inches and quart, pint, fluid ounce, and fluid dram subdivisions thereof, or of the liter, milliliter, or cubic centimeter, and shall express the volume at 68° Fahrenheit (20° Centigrade).

(g) Statements of the quantity of a drug shall contain only such fractions as are generally used in expressing the quantity of such drug. A common fraction shall be reduced to its lowest terms; a decimal fraction shall not be carried out to more than three places, except in the case of a statement of the quantity of an active ingredient in a unit of a drug.

(h) (1) Unless made in accordance with the provisions of subparagraph (2) of this paragraph, a statement of the quantity of a drug, in the terms of weight or measure applicable to such drug under the provisions of paragraph (e) (2) of this section, shall express the number of the largest unit specified in paragraph (f) of this section which is contained in the package (for example, the statement of the label of a package which contains one pint of a drug shall be "1 pint," and not "16 fluid ounces"). Where such number is a whole number and a fraction, there may be substituted for the fraction its equivalent in smaller units, if any smaller is specified in such paragraph (f) (for example, 1¼ pounds may be expressed as "1 pound 4 ounces"). The stated number of any unit which is smaller than the largest unit (specified in such paragraph (f)) contained in the package shall not equal or exceed the number of such smaller units in the next larger unit so specified (for example, instead of "1 quart 16 fluid ounces" the statement shall be "1½ quarts" or "1 quart 1 pint").

(2) In the case of a drug with respect to which there exists an established custom of stating the quantity of the contents as a fraction of a unit, which unit is larger than the quantity contained in the package, or as units smaller than the largest unit contained therein, the statement may be made in accordance with such custom if it is informative to consumers.

(i) The statement of the quantity of a drug or device shall express the minimum quantity, or the average quantity, of the contents of the packages. If the statement is not so qualified as to show definitely that the quantity expressed is the minimum quantity, the statement, except in the case of ampuls, shall be considered to express the average quantity. The statement of the quantity of a drug in ampuls shall be considered to express the minimum quantity.

(j) Where the statement expresses the minimum quantity, no variation below the stated minimum shall be permitted except variations below the stated weight or measure of a drug caused by ordinary and customary exposure, after such drug is introduced into interstate commerce, to conditions which normally occur in good distribution practice and which unavoidably result in decreased weight or measure. Variations above the stated minimum shall not be unreasonably large. In the case of a liquid drug in ampuls the variation above the stated measure shall comply with the excess volume prescribed by the National Formulary for filling of ampuls.

(k) Where the statement does not express the minimum quantity:

(1) Variations from the stated weight or measure of a drug shall be permitted when caused by ordinary and customary exposure, after such drug is introduced into interstate commerce, to conditions which normally occur in good distribution practice and which unavoidably result in change of weight or measure;

(2) Variations from the stated weight, measure, or numerical count of a drug or device shall be permitted when caused by unavoidable deviations in weighing, measuring, or counting the contents of individual packages which occur in good packing practice.

But under subparagraph (2) of this paragraph variations shall not be permitted to such extent that the average of the quantities in the packages comprising a shipment or other delivery of the drug or device is below the quantity stated and no unreasonable shortage in any package shall be permitted, even though overages in other packages in the same shipment or delivery compensate for such shortage.

(l) The extent of variations from the stated quantity of the contents permissible under paragraphs (j) and (k) of this regulation in the case of each shipment or other delivery shall be determined by the facts in such case.

(m) A drug or device shall be exempt from compliance with the requirements of clause (2) of section 502 (b) of the Act if:

(1) The statement of the quantity of the contents, as expressed in terms applicable to such drug or device under the provisions of paragraph (e) (2) of this section, together with all other words, statements, and information required by or under authority of the Act to appear on the label of such drug or device, cannot, because of insufficient label space, be so placed on the label as to comply with the requirements of section 502 (c) of the Act and regulations promulgated thereunder, or

(2) The quantity of the contents of the package, as expressed in terms of numerical count in compliance with paragraph (e) (2) or (3) of this section, is less than six units, and such units can be easily counted without opening the package.

[SEC. 502. A drug or device shall be deemed to be misbranded—]

(c) If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

Regulation. [§1.103] (a) A word, statement, or other information required by or under authority of the Act to appear on the label may lack that prominence and conspicuousness required by section 502 (c) of the Act by reason (among other reasons) of:

(1) The failure of such word, statement, or information to appear on the part or panel of the label which is presented or displayed under customary conditions of purchase;

(2) The failure of such word, statement, or information to appear on two or more parts or panels of the label, each of which has sufficient space therefor, and each of which is so designed as to render it likely to be, under customary conditions of purchase, the part or panel displayed;

(3) The failure of the label to extend over the area of the container or package available for such extension, so as to provide sufficient label space for the prominent placing of such word, statement, or information;

(4) Insufficiency of label space (for the prominent placing of such word, statement, or information) resulting from the use of label space for any word, statement, design, or device which is not required by or under authority of the Act to appear on the label;

(5) Insufficiency of label space (for the prominent placing of such word, statement, or information) resulting from the use of label space to give materially greater conspicuousness to any other word, statement, or information, or to any design or device; or

(6) Smallness or style of type in which such word, statement, or information appears, insufficient background contrast, obscuring designs or vignettes, or crowding with other written, printed, or graphic matter.

(b) No exemption depending on insufficiency of label space, as prescribed in regulations promulgated under section 502 (b) or (e) of the Act, shall apply if such insufficiency is caused by:

(1) The use of label space for any word, statement, design, or device which is not required by or under authority of the Act to appear on the label;

(2) The use of label space to give greater conspicuousness to any word, statement, or other information than is required by section 502 (c) of the Act; or

(3) The use of label space for any representation in a foreign language.

(c) (1) All words, statements, and other information required by or under authority of the Act to appear on the label or labeling shall appear thereon in the English language.

(2) If the label contains any representation in a foreign language, all words, statements, and other information required by or under authority of the Act to appear on the label shall appear thereon in the foreign language.

(3) If the labeling contains any representation in a foreign language, all words, statements, and other information required by or under authority of the Act to appear on the label or labeling shall appear on the labeling in the foreign language.

[Sec. 502. A drug or device shall be deemed to be misbranded—]

(d) If it is for use by man and contains any quantity of the narcotic or hypnotic substance alpha eucaine, barbituric acid, beta-eucaine, bromal, cannabis, carbromal, chloral, coca, cocaine, codeine, heroin, marihuana, morphine, opium, paraldehyde, peyote, or sulphonmethane; or any chemical derivative of such substance, which derivative has been by the Administrator, after investigation, found to be, and by regulations [5] designated as, habit forming; unless its label bears the name, and quantity or proportion of such substance or derivative and in juxtaposition therewith the statement "Warning—May be habit forming".

Regulation. [§1.104] (a) (1) The name of a substance or derivative required to be borne on the label of a drug by section 502 (d) of the Act shall be the common or usual name of such substance or derivative, unless it is designated solely by a name recognized in an official compendium and such designation complies with the provisions of section 502 (*c*).

(2) A statement on the label of a drug of the name of a constituent, which constituent is a chemical derivative of a substance named in section 502 (d) of the Act, shall show the substance from which such constituent is derived and that such constituent is a derivative thereof.

(b) If the drug is in tablet, capsule, ampul, or other unit form, the statement of the quantity or proportion of such substance or derivative contained therein shall express the weight or measure of such substance or derivative in each such unit. If the drug is not in such unit form the statement shall express the weight or measure of such substance or derivative in a specified unit of weight or measure of the drug. Such statement shall be in terms which are informative to the ordinary consumer and user of the drug.

(c) The names and quantities or proportions of all such substances and derivatives, and the statement "Warning—May be habit forming," shall immediately follow (without intervening written, printed, or graphic matter) the name by which such drug is titled in the part or panel of the label thereof which is presented or displayed under customary conditions of purchase.

(d) A drug shall not be considered to be misbranded by reason of failure of its label to bear the statement "Warning—May be habit forming":

(1) If such drug is not suitable for internal use, and is distributed and sold exclusively for such external use as involves no possibility of habit formation; or

[5] 21 CFR Cum. Supp. 145.1; 7 F. R. 460.

(2) If the only substance or derivative subject to section 502 (d) of the Act contained in such drug is chlorobutanol, which is present solely as a preservative and in a quantity not more than 0.5 percent by weight, and such drug is for parenteral use only; or

(3) If the only substance or derivative subject to section 502 (d) of the Act contained in such drug is chlorobutanol, which is present as an analgesic or as an analgesic and a preservative in a quantity not more than 3.0 percent, and such drug contains one or more other active ingredients and is for parenteral use only.

[SEC. 502. A drug or device shall be deemed to be misbranded—]

(e) If it is a drug and is not designated solely by a name recognized in an official compendium unless its label bears (1) the common or usual name of the drug, if such there be; and (2), in case it is fabricated from two or more ingredients, the common or usual name of each active ingredient, including the quantity, kind, and proportion of any alcohol, and also including, whether active or not, the name and quantity or proportion of any bromides, ether, chloroform, acetanilid, acetphenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of any such substances, contained therein: *Provided*, That to the extent that compliance with the requirements of clause (2) of this paragraph is impracticable, exemptions shall be established by regulations promulgated by the Administrator.

Regulation. [§ 1.105] (a) (1) The name of an ingredient, substance, derivative, or preparation required by section 502 (e) (2) of the Act to be borne on the label of a drug shall be the name thereof, which is listed in such section 502 (e) (2) of the Act, or, if not so listed, shall be a specific name and not a collective name. But if an ingredient is an article the name of which is recognized in an official compendium and such article complies with the specifications set forth therefor in such compendium, such ingredient may be designated on the label of such drug by the common or usual name under which such specifications are so set forth.

(2) Where an ingredient contains a substance the quantity or proportion of which is required by section 502 (e) (2) of the Act to appear on the label, and such ingredient is not a derivative or preparation of such substance as defined in paragraph (b) (1) of this section, the label shall bear, in conjunction with the name of the ingredient, a statement of the quantity or proportion of such substance in such drug.

(3) An abbreviation or chemical formula shall not be considered to be a common or usual name. The name "acetophenetidin" shall be considered to be the same as the name "acetphenetidin," "aminopyrine" the same as "amidopyrine." The name "alcohol" without qualification, means ethyl alcohol.

(b) (1) A derivative or preparation of a substance named in section 502 (e) (2) of the Act is an article which is derived or prepared from such substance by any method, including actual or theoretical chemical action.

(2) A statement on the label of a drug of the name of an ingredient thereof, which ingredient is a derivative or preparation of a substance named in section 502 (e) (2) of the Act, shall show the substance from which such ingredient is derived or prepared and that such ingredient is a derivative or preparation thereof.

(c) (1) If the drug is in tablet, capsule, ampul, or other unit form, the statement of the quantity or proportion of a substance, derivative, or preparation contained therein shall express the weight or measure of such substance, derivative, or preparation in each such unit. If the drug is not in such unit form the statement shall express the weight or measure of such substance, derivative, or preparation in a specified unit of weight or measure of the drug, or the percentage of such substance, derivative, or preparation in such drug. Such statement shall be in terms which are informative to the ordinary consumer and user of the drug.

(2) A statement of the percentage of alcohol shall express the percentage of absolute alcohol at 60° Fahrenheit (15.56° Centigrade). A statement of the percentage of a substance, derivative, or preparation other than alcohol shall express the percentage by weight; except that if both the substance, derivative, or preparation and the drug containing it are liquid, the statement may express the percentage by volume at 68° Fahrenheit (20° Centigrade), but in such case the statement shall be so qualified as to show definitely that the percentage is expressed by volume.

(d) In case a statement of the quantity or proportion of a derivative or preparation in a drug is not as informative, to consumers or users of such drug, of the activity or consequences of use thereof as a statement of the quantity or proportion of the substance from which such derivative or preparation is derived or prepared, the quantity or proportion of such substance shall also be stated on the label of such drug.

(e) A label of a drug may be misleading by reason (among other reasons) of:

(1) The order in which the names of ingredients, substances, derivatives, or preparations appear thereon, or the relative prominence otherwise given such names; or

(2) Its failure to reveal the proportion of, or other fact with respect to, an ingredient, substance, derivative, or preparation, when such proportion or other fact is material in the light of the representation that such ingredient, substance, derivative, or preparation is a constituent of such drug.

(f) (1) A drug shall be exempt from the requirements of clause (2) of section 502 (e) of the Act if all words, statements, and other information required by or under authority of the Act to appear on the label of such drug, cannot, because of insufficient label space, be so placed on the label as to comply with the requirements of section 502 (c) of the Act and regulations promulgated thereunder. But such exemption shall be on the condition that, if the omission from the label of the statement of the quantity of the contents affords sufficient space to state legibly thereon all the information required by such clause (2), such statement of the quantity of the contents shall be omitted as authorized by § 1.102 (m) (1), and the information required by such clause (2) shall be so stated as prominently as practicable even though the statement is not of such conspicuousness as to render it likely to be read by the ordinary individual under customary conditions of purchase.

(2) A drug shall be exempt from the requirements of clause (2) of section 502 (e) of the Act with respect to the alkaloids atropine, hyoscine or hyoscyamine contained in such drug, if such alkaloid is contained therein as a constituent of belladonna, hyoscyamus, scopola, stramonium, or other plant material, or any preparation thereof, which was used as an ingredient of such drug, and no practical and accurate method of analysis exists for the quantitative determination of each such alkaloid in such ingredient. But such exemption shall be on the condition that the label of such drug shall state the quantity or proportion of total alkaloids contained therein as constituents of such ingredient.

[Sec. 502. A drug or device shall be deemed to be misbranded—]

(f) Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users: *Provided*, That where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Administrator shall promulgate regulations exempting such drug or device from such requirement.

Regulation. [§ 1.106] (a) Directions for use may be inadequate by reason (among other reasons) of omission, in whole or in part, or incorrect specification of:

(1) Directions for use in all conditions for which such drug or device is prescribed, recommended, or suggested in its labeling, or in its advertising disseminated or sponsored by or on behalf of its manufacturer, packer, or distributor, or in such other conditions, if any there be, for which such drug or device is commonly and effectively used;
(2) Quantity of dose (including quantities for persons of different ages and different physical conditions);
(3) Frequency of administration or application;
(4) Duration of administration or application;
(5) Time of administration or application (in relation to time of meals, time of onset of symptoms, or other time factor);
(6) Route or method of administration or application; or
(7) Preparation for use (shaking, dilution, adjustment of temperature, or other manipulation or process).

(b) Except as otherwise provided by paragraphs (h) and (i) of this section, a shipment or other delivery of a drug or device shall be exempt from the requirements of section 502 (f) (1) of the Act if it complies with all of the following conditions:

(1) Such drug or device, because of its toxicity or other potentiality for harmful effect or the method of its use or the collateral measures necessary to its use, is not generally recognized among experts qualified by scientific training and experience to evaluate its safety and efficacy, as safe and efficacious for use except by or under the supervision of a physician, dentist, or veterinarian.
(2) Such shipment or delivery is to be:
(i) Dispensed by physicians, dentists, or veterinarians in their professional practice;
(ii) Dispensed upon prescriptions issued by physicians, dentists, or veterinarians in their professional practice and under labeling bearing the directions for use specified in such prescriptions;
(iii) Compounded with other substances in filling such prescriptions; or
(iv) Used in the manufacture of another drug or device.
(3) Information adequate for the use of such drug or device by physicians, dentists, or veterinarians, as the case may be, is readily available.
(4) The label of such drug or device (other than surgical instruments and other devices to be used exclusively by physicians, dentists, or veterinarians in their professional practice) bears the statement "Caution: To be dispensed only by or on the prescription of a _____", or "Caution: To be dispensed only by or on the prescription of a _____ or otherwise used only for manufacturing purposes", the blank being filled in with one or more of the words "physician", "dentist", and "veterinarian", as the case may be.
(5) No representation with respect to the conditions for which a drug or device is to be used, or how it is to be used, appears in its labeling except representations:
(i) In printed matter supplied to a physician, dentist, or veterinarian separately from such drug or device;
(ii) Specified in a prescription, which was issued by a physician, dentist, or veterinarian in his professional practice, upon which such drug or device was dispensed; or
(iii) Required by an official compendium.
(6) In the case of a drug which is not designated solely by a name recognized in an official compendium and which is fabricated from two or more ingredients, its label also bears a statement of the quantity or proportion of each active ingredient.

(c) Except as otherwise provided by paragraphs (h) and (i) of this section, a shipment or other delivery of a drug which cannot be exempted under paragraph (b) of this regulation because of the provisions of subparagraph (1) thereof also shall be exempt from the requirements of section 502 (f) (1) of the Act if it complies with all of the conditions set forth in paragraph (b) (4) and (5) of this section and with all of the following additional conditions:

(1) Such drug is not a liquid solution, emulsion, or suspension and is not in tablet, capsule, or other unit form.
(2) The name whereby such drug is designated in its label is recognized in an official compendium.
(3) Such drug is ordinarily compounded with other substances before it is dispensed.
(4) Such shipment or delivery is to be:
(i) Compounded with other substances in filling prescriptions issued by physicians, dentists, or veterinarians in their professional practice; or
(ii) Used in the manufacture of another drug.

(d) Except as otherwise provided by paragraphs (h) and (i) of this section, a shipment or other delivery of a drug which cannot be exempted under paragraph (b) of this section because of the provisions of subparagraph (1) thereof also shall be exempt from the requirements of section 502 (f) (1) of the Act if it is ordinarily used as an inactive ingredient, such as a coloring, emulsifier, excipient, flavoring, lubricant, preservative, or solvent, of other drugs.

(e) Except as otherwise provided by paragraphs (h) and (i) of this section, a shipment or other delivery of a drug or device also shall be exempt from the requirements of section 502 (f) (1) of the Act if it complies with all the conditions set forth in paragraphs (b) (3) and (6) of this section and if such shipment or delivery is made to a physician, dentist, veterinarian, hospital, or clinic to be dispensed by or under the direction of physicians, dentists, or veterinarians in their professional practice.

(f) A shipment or other delivery of a drug or device also shall be exempt from the requirements of section 502 (f) (1) of the Act if it is made to a dealer or manufacturer to be used in the manufacture of another drug or device and its label bears the statement "For manufacturing use only."

(g) A shipment or other delivery of a drug or device also shall be exempt from the requirements of section 502 (f) (1) of the Act with respect to common uses, adequate directions for which are known by the ordinary individual.

(h) No shipment or other delivery of any drug shall be exempt under any provision of this section from any requirement of section 502 (f) (1) of the Act unless its labeling bears the information concerning its use which is contained in the labeling upon the basis of which an application under section 505 of the Act is effective with respect to such drug.

(i) No exemption under any provisions of this regulation shall apply to any shipment or other delivery of:
(1) A drug if its advertising disseminated or sponsored by or on behalf of its manufacturer, packer, or other person responsible for making such shipment or delivery, contains any representation not borne by its labeling and which, if so borne, would make it a new drug;
(2) A drug intended for administration by iontophoresis or by injection into or through the skin or mucous membrane; or
(3) A drug or device if such shipment or delivery is made in the course of the conduct of a business of dispensing drugs or devices pursuant to diagnosis by mail.

(j) If a shipment or other delivery, or any part thereof, of a drug or device which is exempt under paragraph (b), (c), (e), or (f) of this section is disposed of for any purpose other than those specified in such paragraph, such exemption shall expire, with respect to such shipment or delivery or part thereof which is so disposed of, at the beginning of the act of such disposal. The causing of an exemption so to expire shall be considered to be an act which results in such drug or device being misbranded unless, prior to such disposal, it is relabeled to comply with the requirements of section 502 (f) (1) of the Act, or it is disposed of for use otherwise than as a drug or device.

(k) For the purposes of this section:
(1) The term "manufacture" does not include the use of a drug as an ingredient in compounding any prescription issued by a physician, dentist, or veterinarian in his professional practice.
(2) The terms "physician", "dentist", and "veterinarian", as used in relation to the exemption of any drug or device, include only those physicians, dentists, and veterinarians who are licensed by law to administer or apply such drug or device.

[SEC. 502. A drug or device shall be deemed to be misbranded—]

(g) If it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein: *Provided*, That the method of packing may be modified with the consent of the Administrator. Whenever a drug is recognized in both the United States Pharmacopoeia and the Homoeopathic Pharmacopoeia of the United States, it shall be subject to the requirements of the United States Pharmacopoeia with respect to packaging and labeling unless it is labeled and offered for sale as a homoeopathic drug, in which case it shall be subject to the provisions of the Homoeopathic Pharmacopoeia of the United States, and not to those of the United States Pharmacopoeia.

(h) If it has been found by the Administrator to be a drug liable to deterioration, unless it is packaged in such form and manner, and its label bears a statement of such precautions, as the Administrator shall by regulations require as necessary for the protection of the public health. No such regulation shall be established for any drug recognized in an official compendium until the Administrator shall have informed the appropriate body charged with the revision of such compendium of the need for such packaging or labeling requirements and such body shall have failed within a reasonable time to prescribe such requirements.

(i) (1) If it is a drug and its container is so made, formed, or filled as to be misleading; or (2) if it is an imitation of another drug; or (3) if it is offered for sale under the name of another drug.

(j) If it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.

(k) If it is, or purports to be, or is represented as a drug composed wholly or partly of insulin, unless (1) it is from a batch with respect to which a certificate or release has been issued pursuant to section 506, and (2) such certificate or release is in effect with respect to such drug.

Regulation. [§ 1.115] For the purposes of sections 502 (k) and 506 of the Act, the term "insulin" as used therein means the active principle of pancreas which affects the metabolism of carbohydrate in the animal body and which is of value in the treatment of diabetes mellitus.

(l) If it is, or purports to be, or is represented as a drug composed wholly or partly of any kind of penicillin or streptomycin or any derivative thereof, unless (1) it is from a batch with respect to which a certificate or release has been issued pursuant to section 507, and (2) such certificate or release is in effect with respect to such drug: *Provided*, That this paragraph shall not apply to any drug or class of drugs exempted by regulations promulgated under section 507 (c) or (d).

EXEMPTIONS IN CASE OF DRUGS AND DEVICES

SEC. 503. (a) The Administrator is hereby directed to promulgate regulations exempting from any labeling or packing requirement of this Act drugs and devices which are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or

packed, on condition that such drugs and devices are not adulterated or misbranded under the provisions of this Act upon removal from such processing, labeling, or repacking establishment.

Regulation. [§ 1.107] (a) Except as provided by paragraphs (b) and (c) of this section, a shipment or other delivery of a drug or device which is, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantity at an establishment other than that where originally processed or packed, shall be exempt, during the time of introduction into and movement in interstate commerce and the time of holding in such establishment, from compliance with the labeling and packaging requirements of sections 501 (b) and 502 (b), (d), (e), (f), and (g) of the Act if:

(1) The person who introduced such shipment or delivery into interstate commerce is the operator of the establishment where such drug or device is to be processed, labeled, or repacked; or

(2) In case such person is not such operator, such shipment or delivery is made to such establishment under a written agreement, signed by and containing the post-office addresses of such person and such operator, and containing such specifications for the processing, labeling, or repacking, as the case may be, of such drug or device in such establishment as will insure, if such specifications are followed, that such drug or device will not be adulterated or misbranded within the meaning of the Act upon completion of such processing, labeling, or repacking. Such person and such operator shall each keep a copy of such agreement until all such shipment or delivery has been removed from such establishment, and shall make such copies available for inspection at any reasonable hour to any officer or employee of the Agency who requests them.

(b) An exemption of a shipment or other delivery of a drug or device under paragraph (a) (1) of this section shall, at the beginning of the act of removing such shipment or delivery, or any part thereof, from such establishment, become void *ab initio* if the drug or device comprising such shipment, delivery, or part is adulterated or misbranded within the meaning of the Act when so removed.

(c) An exemption of a shipment or other delivery of a drug or device under paragraph (a) (2) of this section shall become void *ab initio* with respect to the person who introduced such shipment or delivery into interstate commerce upon refusal by such person to make available for inspection a copy of the agreement, as required by such subparagraph.

(d) An exemption of a shipment or other delivery of a drug or device under paragraph (a) (2) of this section shall expire:

(1) At the beginning of the act of removing such shipment or delivery, or any part thereof, from such establishment if the drug or device comprising such shipment, delivery, or part is adulterated or misbranded within the meaning of the Act when so removed; or

(2) Upon refusal by the operator of the establishment where such drug or device is to be processed, labeled, or repacked, to make available for inspection a copy of the agreement, as required by such clause.

(e) Except as provided in paragraphs (g) and (h) of this section, a shipment or other delivery of a drug which is subject to section 507 of the Act and which is, in accordance with the practice of the trade, to be processed or repacked in a substantial quantity at an establishment other than that where originally processed or packed shall be exempt from compliance with the labeling requirements of section 502 (f) of the Act during the time such drug is also exempt from the requirements of section 502 (l) of the Act under the provisions of § 146.20 or 146.21 of this chapter.

(f) Except as provided by paragraphs (g) and (h) of this section, a shipment or other delivery of a drug which is subject to section 507 of the Act and which is, in accordance with the practice of the trade, to be labeled in substantial quantity at an establishment other than that where originally processed or packed shall be exempt from compliance with the labeling requirements of section 502 (b), (e) and (f) of the Act during the time such drug is also exempt from the requirements of section 502 (l) of the Act under § 146.18 of this chapter, if the words, statements, and other information required by section 502 (b) and (e) of the Act appear on each shipping container of such drug.

(g) In case the person who introduced such shipment or other delivery into interstate commerce is the operator of the establishment where such drug is to be processed, labeled, or repacked, an exemption of such shipment or delivery under paragraph (e) or (f) of this section shall become void *ab initio* at the beginning of the act of removing such shipment or delivery or any part thereof from such establishment if the drug comprising such shipment, delivery, or part is adulterated or misbranded within the meaning of the Act when so removed.

(h) In case the person who introduced such shipment or delivery into interstate commerce is not the operator of the establishment where such drug is to be processed, labeled, or repacked, an exemption of a shipment or other delivery of such drug under paragraph (e) or (f) of this section shall expire at the beginning of the act of removing such shipment or delivery or any part thereof from such establishment if the drug comprising such shipment, delivery, or part is adulterated or misbranded within the meaning of the Act when so removed.

[SEC. 503] (b) A drug dispensed on a written prescription signed by a physician, dentist, or veterinarian (except a drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail), shall if—

(1) such physician, dentist, or veterinarian is licensed by law to administer such drug, and

(2) such drug bears a label containing the name and place of business of the dispenser, the serial number and date of such prescription, and the name of such physician, dentist, or veterinarian,

be exempt from the requirements of section 502 (b) and (e), and (in case such prescription is marked by the writer thereof as not refillable or its refilling is prohibited by law) of section 502 (d).

CERTIFICATION OF COAL-TAR COLORS FOR DRUGS

SEC. 504. The Administrator shall promulgate regulations [4] providing for the listing of coal-tar colors which are harmless and suitable for use in drugs for purposes of coloring only and for the certification of batches of such colors, with or without harmless diluents.

NEW DRUGS

SEC. 505. (a) No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an application filed pursuant to subsection (b) is effective with respect to such drug.

Regulation. [§1.109] A new drug shall not be deemed to be subject to section 505 of the Act if it is a drug which is licensed under the Public Health Service Act of July 1, 1944 (58 Stat. 682; 42 U. S. C. Supp. V 201 *et seq.*), or under the animal virus-serum-toxin law of March 4, 1913 (37 Stat. 832; 21 U. S. C. 151 *et seq.*). (Sec. 701 (a), 52 Stat. 1055; 21 U. S. C. 371).

[SEC. 505] (b) Any person may file with the Administrator an application with respect to any drug subject to the provisions of subsection (a). Such person shall submit to the Administrator as a part of the application (1) full reports of investigations which have been made to show whether or not such drug is safe for use; (2) a full list of the articles used as components of such drug; (3) a full statement of the composition of such drug; (4) a full description of the methods used in, and the facilities and controls used for, the manufacture, process-

[4] Service and Regulatory Announcements, Food, Drug, and Cosmetic No. 3.

ing, and packing of such drug; (5) such samples of such drug and of the articles used as components thereof as the Administrator may require; and (6) specimens of the labeling proposed to be used for such drug.

Regulation. [§ 1.110] (a) Each application submitted for filing with the Administrator shall be in duplicate. If any part of the application is in a foreign language, an accurate and complete English translation shall be appended to such part.

(b) An application shall not be accepted for filing if only one copy is submitted or if it is incomplete on its face in that:

(1) It does not contain all the matter required by clauses (1), (2), (3), (4), and (6) of section 505 (b) of the Act;

(2) It does not state the conditions under which the drug is to be used; or

(3) The specimens of labeling proposed for use upon or within the retail package do not expressly or by reference to a brochure or other printed matter prescribe, recommend, or suggest the use of such drug under such conditions.

The Food and Drug Administration shall notify the applicant of such nonacceptance and the reason therefor and, in case of incompleteness as to matter required by any clause of section 505 (b), shall specify such clause. Otherwise the date on which an application is received by the Agency shall be considered to be the date on which such application is filed, and the Food and Drug Administration shall notify the applicant of such date. If the applicant withdraws his application, such application shall be considered as not having been filed.

(c) The applicant may file an amendment to an application which has been filed and is pending before the Administrator, but in such case the unamended application shall be considered as having been withdrawn and the amended application shall be considered as having been filed on the date on which the amendment is received by the Agency. The Food and Drug Administration shall notify the applicant of such date.

(d) After an application has become effective with respect to a drug, the applicant may file a supplemental application with respect thereto, setting forth any proposed change in the conditions under which such drug is to be used, in the labeling thereof, in any circumstance relating to its production, or in any other information contained in the effective application. Such supplemental application may omit statements made in the effective application concerning which no change is proposed.

[SEC. 505] (c) An application provided for in subsection (b) shall become effective on the sixtieth day after the filing thereof unless prior to such day the Administrator by notice to the applicant in writing postpones the effective date of the application to such time (not more than one hundred and eighty days after the filing thereof) as the Administrator deems necessary to enable him to study and investigate the application.

Regulation. [§ 1.111). If the Administrator determines, before the date prescribed by section 505 (c) of the Act for an application to become effective, that he has no cause to issue an order under section 505 (d) of the Act refusing to permit such application to become effective, the Food and Drug Administration shall so notify the applicant in writing and such application shall become effective on the date of the notification.

[SEC. 505] (d) If the Administrator finds, after due notice to the applicant and giving him an opportunity for a hearing, that (1) the investigations, reports of which are required to be submitted to the Administrator pursuant to subsection (b), do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; (2) the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such

conditions; (3) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity; or (4) upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him with respect to such drug, he has insufficient information to determine whether such drug is safe for use under such conditions, he shall, prior to the effective date of the application, issue an order refusing to permit the application to become effective.

Regulation. [§ 1.112]. The information contained in an application may be insufficient for the Administrator to determine whether a drug is safe for use if it fails to include (among other things) a statement showing whether the drug is to be exempt under any provision of regulation § 1.106, as amended, promulgated pursuant to section 502 (f) of the Act, from the requirement that its labeling bear adequate directions for use. If the drug is to be so exempt, the information may also be insufficient if:

(1) The specimen label of the drug fails to incorporate by reference a specifically identified brochure or other printed matter containing information adequate for the use of such drug by physicians, dentists, or veterinarians, as the case may be;

(2) Such label fails to state that the drug is to be used as shown in such brochure or printed matter and that such brochure or printed matter will be sent to physicians, dentists, or veterinarians, as the case may be, on request;

(3) The application fails to contain copies of such brochure or printed matter; or

(4) The application fails to show that such brochure or printed matter is readily available to physicians, dentists, or veterinarians, as the case may be, or, if not, that it is to be made so when the application becomes effective.

(e) The effectiveness of an application with respect to any drug shall, after due notice and opportunity for hearing to the applicant, by order of the Administrator be suspended if the Administrator finds (1) that clinical experience, tests by new methods, or tests by methods not deemed reasonably applicable when such application became effective show that such drug is unsafe for use under the conditions of use upon the basis of which the application became effective, or (2) that the application contains any untrue statement of a material fact. The order shall state the findings upon which it is based.

Regulation. [§ 1.113]. Among the reasons why an application may contain an untrue statement of a material fact are changes in:

(1) Conditions of use prescribed, recommended, or suggested by the applicant for the drug from the conditions of such use stated in the application;

(2) Articles used as components of the drug from those listed in the application:

(3) Composition of the drug from that stated in the application;

(4) Methods used in, or the facilities or controls used for, the manufacture, processing, or packing of the drug from such methods, facilities, and controls described in the application; and

(5) Labeling from the specimens contained in the application.

(f) An order refusing to permit an application with respect to any drug to become effective shall be revoked whenever the Administrator finds that the facts so require.

(g) Orders of the Administrator issued under this section shall be served (1) in person by any officer or employee of the Agency designated by the Administrator or (2) by mailing the order by registered mail addressed to the applicant or respondent at his last-known address in the records of the Administrator.

(h) An appeal may be taken by the applicant from an order of the Administrator refusing to permit the application to become effective, or suspending the effectiveness of the application. Such appeal shall be taken by filing in the district court of the United States within any district wherein such applicant resides or has his principal place of business, or in the District Court of the United States for the District of Columbia, within sixty days after the entry of such order, a written petition praying that the order of the Administrator be set aside. A copy of such petition shall be forthwith served upon the Administrator, or upon any officer designated by him for that purpose, and thereupon the Administrator shall certify and file in the court a transcript of the record upon which the order complained of was entered. Upon the filing of such transcript such court shall have exclusive jurisdiction to affirm or set aside such order. No objection to the order of the Administrator shall be considered by the court unless such objection shall have been urged before the Administrator or unless there were reasonable grounds for failure so to do. The finding of the Administrator as to the facts, if supported by substantial evidence, shall be conclusive. If any person shall apply to the court for leave to adduce additional evidence, and shall show to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for failure to adduce such evidence in the proceeding before the Administrator, the court may order such additional evidence to be taken before the Administrator and to be adduced upon the hearing in such manner and upon such terms and conditions as to the court may seem proper. The Administrator may modify his findings as to the facts by reason of the additional evidence so taken, and he shall file with the court such modified findings which, if supported by substantial evidence, shall be conclusive, and his recommendation, if any, for the setting aside of the original order. The judgment and decree of the court affirming or setting aside any such order of the Administrator shall be final, subject to review as provided in sections 128, 239, and 240 of the Judicial Code, as amended (U. S. C., 1934 ed., title 28, secs. 225, 346, and 347), and in section 7, as amended, of the Act entitled "An Act to establish a Court of Appeals for the District of Columbia", approved February 9, 1893 (D. C. Code, title 18, sec. 26). The commencement of proceedings under this subsection shall not, unless specifically ordered by the court to the contrary, operate as a stay of the Administrator's order.

(i) The Administrator shall promulgate regulations for exempting from the operation of this section drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety of drugs.

Regulation. [§ 1.114] (a) Except as provided by paragraph (b) of this section a shipment or other delivery of a new drug shall be exempt from the operation of section 505 (a) of the Act if all of the following conditions are complied with:

(1) The label of such drug bears the statement "Caution: New drug—Limited by Federal law to investigational use."

(2) Such shipment or delivery is made only to, and solely for investigational use by or under the direction of, an expert qualified by scientific training and experience to investigate the safety of such drug.

(3) The person who introduced such shipment or delivery into interstate commerce obtains, prior to the introduction, a statement signed by such expert showing that he has adequate facilities for the investigation to be conducted by him, and that such drug will be used solely by him or under his direction for the investigation, unless and until an application becomes effective with respect to such drug under section 505 of the Act. This subparagraph shall not apply when such shipment or delivery is made to an agency of the Government of the United States (including the National Research Council), or of any State or municipality, whose official functions involve investigations of new drugs by such experts.

(4) Such person keeps the statement referred to in subparagraph (3) of this paragraph, and complete records showing the date, quantity, and batch or code mark (if any), of each such shipment and delivery.

(5) Such person makes all records and statements referred to in subparagraphs (3) and (4) of this paragraph available for inspection upon the request of any officer or employee of the Agency at any reasonable hour until 3 years after the introduction of such shipment or delivery into interstate commerce.

(b) A shipment or other delivery of a new drug which is being imported or offered for import into the United States shall be exempt from the operation of section 505 (a) of the Act if all of the following conditions are complied with:

(1) The label of such drug bears the statement "Caution: New Drug—Limited by United States law to investigational use."

(2) The importer of all such shipments or deliveries is an agent of the foreign exporter, residing in the United States, or the operator of an establishment in the United States which has facilities for regularly investigating the safety of such drugs, which facilities are manned by experts qualified by scientific training and experience to conduct such investigation.

(3) Such operator uses such drug solely for such investigation in such establishment, or such operator or agent otherwise disposes of such drug only to, and solely for investigational use by or under the direction of, such an expert other than one in such establishment.

(4) Such importer, prior to disposing of any of such drug to such an expert, obtains a statement signed by such expert showing that he has adequate facilities for the investigation to be conducted by him, and that such drug will be used solely by him or under his direction for the investigation, unless and until an application becomes effective with respect to such drug under section 505 of the Act. This subparagraph shall not apply to any shipment or delivery or part thereof disposed of by such importer to an agency of the Government of the United States (including the National Research Council) or of any State or municipality whose official functions involve investigations of new drugs by such experts.

(5) Such importer keeps the statement referred to in subparagraph (4) of this paragraph and complete records showing the date, quantity, and batch or code marks (if any), of each such shipment and delivery and the disposition thereof.

(6) Such importer makes all statements and records referred to in subparagraphs (4) and (5) of this paragraph available for inspection upon the request of any officer or employee of the Agency at any reasonable hour until 3 years after disposition by such importer of the lot of such drug to which such statement and records relate.

(c) An exemption under paragraph (a) or (b) of this section shall become void *ab initio* if any record or statement required by such paragraph to be kept and made available for inspection is not kept or made available as so required.

(d) An exemption under paragraph (a) or (b) of this section shall expire with respect to any exempted shipment or delivery or part thereof which has been supplied to an expert who has signed the statement referred to in paragraph (a) (3) or (b) (4) of this section and which is used otherwise than in accordance with such signed statement.

(e) An exemption under paragraph (b) of this section shall become void *ab initio* if the exempted shipment or delivery or any part thereof is disposed of otherwise than as provided by subparagraph (3) of such paragraph.

(f) No exemption under paragraph (b) of this section shall apply to any shipment or delivery to such importer if such importer, within 3 years prior to the offering of such shipment or delivery for import, has caused an exemption to become void as provided by paragraph (c) or (e) of this section.

CERTIFICATION OF DRUGS CONTAINING INSULIN

SEC. 506. (a) The Federal Security Administrator, pursuant to regulations[6] promulgated by him, shall provide for the certification of batches of drugs composed wholly or partly of insulin. A batch of any such drug shall be certified if such drug has such characteristics of identity and such batch has such characteristics of strength, quality, and purity, as the Administrator prescribes in such regulations as necessary to adequately insure safety and efficacy of use, but shall not otherwise be certified. Prior to the effective date of such regulations the Administrator, in lieu of certification, shall issue a release for any batch which, in his judgment, may be released without risk as to the safety and efficacy of its use. Such release shall prescribe the date of its expiration and other conditions under which it shall cease to be effective as to such batch and as to portions thereof.

(b) Regulations providing for such certification shall contain such provisions as are necessary to carry out the purposes of this section, including provisions prescribing (1) standards of identity and of strength, quality, and purity; (2) tests and methods of assay to determine compliance with such standards; (3) effective periods for certificates, and other conditions under which they shall cease to be effective as to certified batches and as to portions thereof; (4) administration and procedure; and (5) such fees, specified in such regulations, as are necessary to provide, equip, and maintain an adequate certification service. Such regulations shall prescribe no standard of identity or of strength, quality, or purity for any drug different from the standard of identity, strength, quality, or purity set forth for such drug in an official compendium.

(c) Such regulations, insofar as they prescribe tests or methods of assay to determine strength, quality, or purity of any drug, different from the tests or methods of assay set forth for such drug in an official compendium, shall be prescribed, after notice and opportunity for revision of such compendium, in the manner provided in the second sentence of section 501 (b). The provisions of subsections (e), (f), and (g) of section 701 shall be applicable to such portion of any regulation as prescribes any such different test or method, but shall not be applicable to any other portion of any such regulation.

[6] 21 CFR, 1943 Supp., 144.1 *et seq.;* 8 F. R. 11837.

CERTIFICATION OF DRUGS CONTAINING PENICILLIN OR STREPTOMYCIN

SEC. 507. (a) The Federal Security Administrator, pursuant to regulations[7] promulgated by him, shall provide for the certification of batches of drugs composed wholly or partly of any kind of penicillin or streptomycin or any derivative thereof. A batch of any such drug shall be certified if such drug has such characteristics of identity and such batch has such characteristics of strength, quality, and purity, as the Administrator prescribes in such regulations as necessary to adequately insure safety and efficacy of use, but shall not otherwise be certified. Prior to the effective date of such regulations the Administrator, in lieu of certification, shall issue a release for any batch which, in his judgment, may be released without risk as to the safety and efficacy of its use. Such release shall prescribe the date of its expiration and other conditions under which it shall cease to be effective as to such batch and as to portions thereof.

(b) Regulations providing for such certifications shall contain such provisions as are necessary to carry out the purposes of this section, including provisions prescribing (1) standards of identity and of strength, quality, and purity; (2) tests and methods of assay to determine compliance with such standards; (3) effective periods for certificates, and other conditions under which they shall cease to be effective as to certified batches and as to portions thereof; (4) administration and procedure; and (5) such fees, specified in such regulations, as are necessary to provide, equip, and maintain an adequate certification service. Such regulations shall prescribe only such tests and methods of assay as will provide for certification or rejection within the shortest time consistent with the purposes of this section.

(c) Whenever in the judgment of the Administrator, the requirements of this section and of section 502 (l) with respect to any drug or class of drugs are not necessary to insure safety and efficacy of use, the Administrator shall promulgate regulations exempting such drug or class of drugs from such requirements.

(d) The Administrator shall promulgate regulations exempting from any requirement of this section and of section 502 (l), (1) drugs which are to be stored, processed, labeled, or repacked at establishments other than those where manufactured, on condition that such drugs comply with all such requirements upon removal from such establishments; (2) drugs which conform to applicable standards of identity, strength, quality, and purity prescribed by these regulations and are intended for use in manufacturing other drugs; and (3) drugs which are intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and efficacy of drugs.

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[7] Compilation of Regulations for Tests and Methods of Assay and Certification of Antibiotic Drugs: Vol. 1, Tests and Methods of Assay; Vol. 2, Certification of Antibiotic Drugs.

(e) No drug which is subject to section 507 shall be deemed to be subject to any provision of section 505. Compliance of any drug subject to section 502 (l) or 507 with sections 501 (b) and 502 (g) shall be determined by the application of the standards of strength, quality, and purity, the tests and methods of assay, and the requirements of packaging and labeling, respectively, prescribed by regulations promulgated under section 507.

(f) Any interested person may file with the Administrator a petition proposing the issuance, amendment, or repeal of any regulation contemplated by this section. The petition shall set forth the proposal in general terms and shall state reasonable grounds therefor. The Administrator shall give public notice of the proposal and an opportunity for all interested persons to present their views thereon, orally or in writing, and as soon as practicable thereafter shall make public his action upon such proposal. At any time prior to the thirtieth day after such action is made public any interested person may file objections to such action, specifying with particularity the changes desired, stating reasonable grounds therefor, and requesting a public hearing upon such objections. The Administrator shall thereupon, after due notice, hold such public hearing. As soon as practicable after completion of the hearing, the Administrator shall by order make public his action on such objections. The Administrator shall base his order only on substantial evidence of record at the hearing and shall set forth as part of the order detailed findings of fact on which the order is based. The order shall be subject to the provisions of section 701 (f) and (g).

CHAPTER VI—COSMETICS

ADULTERATED COSMETICS

Sec. 601. A cosmetic shall be deemed to be adulterated—

(a) If it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual: *Provided*, That this provision shall not apply to coal-tar hair dye, the label of which bears the following legend conspicuously displayed thereon: "Caution—This product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness.", and the labeling of which bears adequate directions for such preliminary testing. For the purposes of this paragraph and paragraph (e) the term "hair dye" shall not include eyelash dyes or eyebrow dyes.

Regulation. [§ 1.200] The term "coal-tar hair dye" includes all articles containing any coal-tar color or intermediate which color or intermediate alters the color of the hair when such articles are applied to the hair under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual.

[Sec. 601. A cosmetic shall be deemed to be adulterated—]

(b) If it consists in whole or in part of any filthy, putrid, or decomposed substance.

(c) If it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

(d) If its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health.

(e) If it is not a hair dye and it bears or contains a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by section 604.

MISBRANDED COSMETICS

SEC. 602. A cosmetic shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular.

Regulation. [§ 1.201] (a) Among representations in the labeling of a cosmetic which render such cosmetic misbranded is a false or misleading representation with respect to another cosmetic or a food, drug, or device.

(b) The labeling of a cosmetic which contains two or more ingredients may be misleading by reason (among other reasons) of the designation of such cosmetic in such labeling by a name which includes or suggests the name of one or more but not all such ingredients, even though the names of all such ingredients are stated elsewhere in the labeling.

[SEC. 602. A cosmetic shall be deemed to be misbranded—]

(b) If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: *Provided*, That under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Administrator.

Regulation. [§ 1.202] (a) If a cosmetic is not manufactured by the person whose name appears on the label, the name shall be qualified by a phrase which reveals the connection such person has with such cosmetic such as "Manufactured for and Packed by _____", "Distributed by _____", or other similar phrase which expresses the facts.

(b) The statement of the place of business shall include the street address, if any, of such place, unless such street address is shown in a current city directory or telephone directory.

(c) Where a person manufactures, packs, or distributes a cosmetic at a place other than his principal place of business, the label may state the principal place of business in lieu of the actual place where each package of such cosmetic was manufactured or packed or is to be distributed, if such statement is not misleading in any particular.

(d) The requirement that the label shall contain the name and place of business of the manufacturer, packer, or distributor shall not be considered to relieve any cosmetic from the requirement that its label shall not be misleading in any particular.

(e) (1) The statement of the quantity of the contents shall reveal the quantity of cosmetic in the package, exclusive of wrappers and other material packed with such cosmetic.

(2) The statement shall be expressed in the terms of weight, measure, numerical count, or a combination of numerical count and weight or measure, which are generally used by consumers to express quantity of such cosmetic and which give accurate information as to the quantity thereof. But if no general consumer usage in expressing accurate information as to the quantity of such cosmetic exists, the statement shall be in terms of liquid measure if the cosmetic is liquid, or in terms of weight if the cosmetic is solid, semisolid, or viscous, or in such terms of numerical count, or numerical count and weight or measure, as will give accurate information as to the quantity of the cosmetic in the package.

(f) (1) A statement of weight shall be in terms of the avoirdupois pound and ounce. A statement of liquid measure shall be in terms of the United States gallon of 231 cubic inches and quart, pint, and fluid ounce subdivisions thereof, and shall express the volume at 68° Fahrenheit (20° Centigrade). However, in the case of an export shipment, the statement may be in terms of a system of weight or measure in common use in the country to which such shipment is exported.

(2) A statement of weight or measure in the terms specified in subparagraph (1) of this paragraph may be supplemented by a statement in terms of the metric system of weight or measure.

(3) Unless an unqualified statement of numerical count gives accurate information as to the quantity of cosmetic in the package, it shall be supplemented by such statement of weight, measure, or size of the individual units of the cosmetic as will give such information.

(g) Statements shall contain only such fractions as are generally used in expressing the quantity of the cosmetic. A common fraction shall be reduced to its lowest terms; a decimal fraction shall not be carried out to more than two places.

(h) (1) If the quantity of cosmetic in the package equals or exceeds the smallest unit of weight or measure which is specified in paragraph (f) of this section, and which is applicable to such cosmetic under the provisions of paragraph (e) (2) of this section, the statement shall express the number of the largest of such units contained in the package (for example, the statement on the label of a package which contains one pint of cosmetic shall be "1 pint" and not "16 fluid ounces"), unless the statement is made in accordance with the provisions of subparagraph (2) of this paragraph. Where such number is a whole number and a fraction, there may be substituted for the fraction its equivalent in smaller units, if any smaller is specified in such paragraph (f) (for examples, 1¾ quarts may be expressed as "1 quart 1½ pints" or "1 quart 1 pint 8 fluid ounces"; 1¼ pounds may be expressed as "1 pound 4 ounces"). The stated number of any unit which is smaller than the largest unit (specified in such paragraph (f)) contained in the package shall not equal or exceed the number of such smaller units in the next larger unit so specified (for examples, instead of "1 quart 16 fluid ounces" the statement shall be "1½ quarts" or "1 quart 1 pint"; instead of "24 ounces" the statement shall be "1½ pounds" or "1 pound 8 ounces").

(2) In the case of a cosmetic with respect to which there exists an established custom of stating the quantity of the contents as a fraction of a unit, which unit is larger than the quantity contained in the package, or as units smaller than the largest unit contained therein, the statement may be made in accordance with such custom if it is informative to consumers.

(i) The statement shall express the minimum quantity, or the average quantity, of the contents of the packages. If the statement is not so qualified as to show definitely that the quantity expressed is the minimum quantity, the statement shall be considered to express the average quantity.

(j) Where the statement expresses the minimum quantity, no variation below the stated mimimum shall be permitted except variations below the stated weight or measure caused by ordinary and customary exposure, after the cosmetic is introduced into interstate commerce, to conditions which normally occur in good distribution practice and which unavoidably result in decreased weight or measure. Variations above the stated minimum shall not be unreasonably large.

(k) Where the statement does not express the minimum quantity:

(1) Variations from the stated weight or measure shall be permitted when caused by ordinary and customary exposure, after the cosmetic is introduced into interstate commerce, to conditions which normally occur in good distribution practice and which unavoidably result in change of weight or measure.

(2) Variations from the stated weight, measure, or numerical count shall be permitted when caused by unavoidable deviations in weighing, measuring, or counting individual packages which occur in good packing practice. But under subparagraph (2) of this paragraph variations shall not be permitted to such extent that the average of the quantities in the packages comprising a shipment or other delivery of the cosmetic is below the quantity stated, and no unreasonable shortage in any package shall be permitted, even though overages in other packages in the same shipment or delivery compensate for such shortage.

(l) The extent of variations from the stated quantity of the contents permissible under paragraphs (j) and (k) of this section in the case of each shipment or other delivery shall be determined by the facts in such case.

(m) A cosmetic shall be exempt from compliance with the requirements of clause (2) of section 602 (b) of the Act if the quantity of the contents of the package, as expressed in terms applicable to such cosmetic under the provisions of paragraph (e) (2) of this section, is less than one-fourth ounce avoirdupois, or less than one-eighth fluid ounce, or (in case the units of the cosmetic can be easily counted without opening the package) less than six units.

[SEC. 602. A cosmetic shall be deemed to be misbranded—]

(c) If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

Regulation. [§ 1.203] (a) A word, statement, or other information required by or under authority of the Act to appear on the label may lack that prominence and conspicuousness required by section 602 (c) of the Act by reason (among other reasons) of:

(1) The failure of such word, statement, or information to appear on the part or panel of the label which is presented or displayed under customary conditions of purchase;

(2) The failure of such word, statement, or information to appear on two or more parts or panels of the label each of which has sufficient space therefor, and each of which is so designed as to render it likely to be, under customary conditions of purchase, the part or panel displayed;

(3) The failure of the label to extend over the area of the container or package available for such extension, so as to provide sufficient label space for the prominent placing of such word, statement, or information;

(4) Insufficiency of label space (for the prominent placing of such word, statement, or information) resulting from the use of label space for any word, statement, design, or device which is not required by or under authority of the Act to appear on the label;

(5) Insufficiency of label space (for the prominent placing of such word, statement, or information) resulting from the use of label space to give materially greater conspicuousness to any other word, statement, or information, or to any design or device;

(6) Smallness or style of type in which such word, statement, or information appears, insufficient background contrast, obscuring designs or vignettes, or crowding with other written, printed, or graphic matter.

(b) (1) All words, statements, and other information required by or under authority of the Act to appear on the label or labeling shall appear thereon in the English language.

(2) If the label contains any representation in a foreign language, all words, statements, and other information required by or under authority of the Act to appear on the label shall appear thereon in the foreign language.

[SEC. 602. A cosmetic shall be deemed to be misbranded—]

(d) If its container is so made, formed, or filled as to be misleading.

REGULATIONS MAKING EXEMPTIONS

SEC. 603. The Administrator shall promulgate regulations exempting from any labeling requirement of this Act cosmetics which are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such cosmetics are not adulterated or misbranded under the provisions of this Act upon removal from such processing, labeling, or repacking establishment.

Regulation. [§ 1.204] (a) Except as provided by paragraphs (b) and (c) of this section, a shipment or other delivery of a cosmetic which is, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantity at an establishment other than that where originally processed or packed, shall be exempt, during the time of introduction into and movement in interstate commerce and the time of holding in such establishment, from compliance with the labeling requirements of sections 601 (a) and 602 (b) of the Act if:

(1) The person who introduced such shipment or delivery into interstate commerce is the operator of the establishment where such cosmetic is to be processed, labeled, or repacked; or

(2) In case such person is not such operator, such shipment or delivery is made to such establishment under a written agreement, signed by and containing the post-office addresses of such person and such operator, and containing such specifications for the processing, labeling or repacking, as the case may be, of such cosmetic in such establishment as will insure, if such specifications are followed, that such cosmetic will not be adulterated or misbranded within the meaning of the Act upon completion of such processing, labeling, or repacking. Such person and such operator shall each keep a copy of such agreement until all such shipment or delivery has been removed from such establishment, and shall make such copies available for inspection at any reasonable hour to any officer or employee of the Agency who requests them.

(b) An exemption of a shipment or other delivery of a cosmetic under paragraph (a) (1) of this section shall, at the beginning of the act of removing such shipment or delivery, or any part thereof, from such establishment, become void *ab initio* if the cosmetic comprising such shipment, delivery, or part is adulterated or misbranded within the meaning of the Act when so removed.

(c) An exemption of a shipment or other delivery of a cosmetic under paragraph (a) (2) of this section shall become void *ab initio* with respect to the person who introduced such shipment or delivery into interstate commerce upon refusal by such person to make available for inspection a copy of the agreement, as required by such clause.

(d) An exemption of a shipment or other delivery of a cosmetic under paragraph (a) (2) of this section shall expire:

(1) At the beginning of the act of removing such shipment or delivery, or any part thereof, from such establishment if the cosmetic comprising such shipment, delivery, or part is adulterated or misbranded within the meaning of the Act when so removed; or

(2) Upon refusal by the operator of the establishment where such cosmetic is to be processed, labeled, or repacked, to make available for inspection a copy of the agreement, as required by such clause.

CERTIFICATION OF COAL-TAR COLORS FOR COSMETICS

SEC. 604. The Administrator shall promulgate regulations [4] providing for the listing of coal-tar colors which are harmless and suitable for use in cosmetics and for the certification of batches of such colors, with or without harmless diluents.

[4] Service and Regulatory Announcements, Food, Drug, and Cosmetic No. 3.

CHAPTER VII--GENERAL ADMINISTRATIVE PROVISIONS

REGULATIONS AND HEARINGS

SEC. 701. (a) The authority to promulgate regulations for the efficient enforcement of this Act, except as otherwise provided in this section, is hereby vested in the Administrator.

(b) The Secretary of the Treasury and the Federal Security Administrator shall jointly prescribe regulations for the efficient enforcement of the provisions of section 801, except as otherwise provided therein. Such regulations shall be promulgated in such manner and take effect at such time, after due notice, as the Federal Security Administrator shall determine.

(c) Hearings authorized or required by this Act shall be conducted by the Administrator or such officer or employee as he may designate for the purpose.

(d) The definitions and standards of identity promulgated in accordance with the provisions of this Act shall be effective for the purposes of the enforcement of this Act, notwithstanding such definitions and standards as may be contained in other laws of the United States and regulations promulgated thereunder.

(e) The Administrator, on his own initiative or upon an application of any interested industry or substantial portion thereof stating reasonable grounds therefor, shall hold a public hearing [8] upon a proposal to issue, amend, or repeal any regulation contemplated by any of the following sections of this Act: 401, 403 (j), 404 (a), 406 (a) and (b), 501 (b), 502 (d), 502 (h), 504, and 604. The Administrator shall give appropriate notice of the hearing, and the notice shall set forth the proposal in general terms and specify the time and place for a public hearing to be held thereon not less than thirty days after the date of the notice, except that the public hearing on regulations under section 404 (a) may be held within a reasonable time, to be fixed by the Administrator, after notice thereof. At the hearing any interested person may be heard in person or by his representative. As soon as practicable after completion of the hearing, the Administrator shall by order make public his action in issuing, amending, or repealing the regulation or determining not to take such action. The Administrator shall base his order only on substantial evidence of record at the hearing and shall set forth as part of the order detailed findings of fact on which the order is based. No such order shall take effect prior to the ninetieth day after it is issued, except that if the Administrator finds that emergency conditions exist necessitating an earlier effective date, then the Administrator shall specify in the order his findings as to such conditions and the order shall take effect at such earlier date as the Administrator shall specify therein to meet the emergency.

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[8] 21 CFR Cum. Supp. 2.701 *et seq.;* 5 F. R. 2379.

(f) (1) In a case of actual controversy as to the validity of any order under subsection (e), any person who will be adversely affected by such order if placed in effect may at any time prior to the ninetieth day after such order is issued file a petition with the Circuit Court of Appeals of the United States for the circuit wherein such person resides or has his principal place of business, for a judicial review of such order. The summons and petition may be served at any place in the United States. The Administrator, promptly upon service of the summons and petition, shall certify and file in the court the transcript of the proceedings and the record on which the Administrator based his order.

(2) If the petitioner applies to the court for leave to adduce additional evidence, and shows to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceeding before the Administrator, the court may order such additional evidence (and evidence in rebuttal thereof) to be taken before the Administrator, and to be adduced upon the hearing, in such manner and upon such terms and conditions as to the court may seem proper. The Administrator may modify his findings as to the facts, or make new findings, by reason of the additional evidence so taken, and he shall file such modified or new findings, and his recommendation, if any, for the modification or setting aside of his original order, with the return of such additional evidence.

(3) The court shall have jurisdiction to affirm the order, or to set it aside in whole or in part, temporarily or permanently. If the order of the Administrator refuses to issue, amend, or repeal a regulation and such order is not in accordance with law the court shall by its judgment order the Administrator to take action, with respect to such regulation, in accordance with law. The findings of the Administrator as to the facts, if supported by substantial evidence, shall be conclusive.

(4) The judgment of the court affirming or setting aside, in whole or in part, any such order of the Administrator shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in sections 239 and 240 of the Judicial Code, as amended.

(5) Any action instituted under this subsection shall survive notwithstanding any change in the person occupying the office of Administrator or any vacancy in such office.

(6) The remedies provided for in this subsection shall be in addition to and not in substitution for any other remedies provided by law.

(g) A certified copy of the transcript of the record and proceedings under subsection (e) shall be furnished by the Administrator to any interested party at his request, and payment of the costs thereof, and shall be admissible in any criminal, libel for condemnation, exclusion of imports, or other proceeding arising under or in respect to this Act, irrespective of whether proceedings with respect to the order have previously been instituted or become final under subsection (f).

EXAMINATIONS AND INVESTIGATIONS

SEC. 702. (a) The Administrator is authorized to conduct examinations and investigations for the purposes of this Act through officers and employees of the Agency or through any health, food, or drug officer or employee of any State, Territory, or political subdivision thereof, duly commissioned by the Administrator as an officer of the Agency. In the case of food packed in a Territory the Administrator shall attempt to make inspection of such food at the first point of entry within the United States when, in his opinion and with due regard to the enforcement of all the provisions of this Act, the facilities at his disposal will permit of such inspection. For the purposes of this subsection the term "United States" means the States and the District of Columbia.

(b) Where a sample of a food, drug, or cosmetic is collected for analysis under this Act the Administrator shall, upon request, provide a part of such official sample for examination or analysis by any person named on the label of the article, or the owner thereof, or his attorney or agent; except that the Administrator is authorized, by regulations, to make such reasonable exceptions from, and impose such reasonable terms and conditions relating to, the operation of this subsection as he finds necessary for the proper administration of the provisions of this Act.

Regulation. [§ 1.700] (a) (1) When any officer or employee of the Agency collects a sample of a food, drug, or cosmetic for analysis under the Act, the sample shall be designated as an official sample if records or other evidence is obtained by him or any other officer or employee of the Agency indicating that the shipment or other lot of the article from which such sample was collected was introduced or delivered for introduction into interstate commerce, or was in or was received in interstate commerce, or was manufactured within a Territory. Only samples so designated by an officer or employee of the Agency shall be considered to be official samples.

(2) For the purpose of determining whether or not a sample is collected for analysis, the term "analysis" includes examinations and tests.

(3) The owner of a food, drug, or cosmetic of which an official sample is collected is the person who owns the shipment or other lot of the article from which the sample is collected.

(b) When an officer or employee of the Agency collects an official sample of a food, drug, or cosmetic for analysis under the Act, he shall collect at least twice the quantity estimated by him to be sufficient for analysis, unless:

(1) The amount of the article available and reasonably accessible for sampling is less than twice the quantity so estimated;

(2) The cost of twice the quantity so estimated exceeds $10;

(3) The article is perishable;

(4) The sample is collected from a shipment or other lot which is being imported or offered for import into the United States;

(5) The sample is collected from a person named on the label of the article, or his agent, and such person is also the owner of the article;

(6) The sample is collected from the owner of the article, or his agent, and such article bears no label or, if it bears a label, no person is named thereon; or

(7) The analysis consists principally of rapid analytical procedures, organoleptic examination, or other field inspection examinations or tests, made at the place where the sample is collected or in a mobile or temporary laboratory.

In addition to the quantity of sample prescribed above the officer or employee shall, if practicable, collect as part of the sample such further amount of the article as he estimates to be sufficient for use as exhibits in the trial of any case that may arise under the Act based on the sample.

(c) After the Food and Drug Administration has completed such analysis of an official sample of a food, drug, or cosmetic as it determines, in the course of analysis and interpretation of analytical results, to be adequate to establish the respects, if any, in which the article is adulterated or misbranded within the meaning of the Act, or otherwise subject to the prohibitions of the Act, and has reserved an amount of the article it estimates to be adequate for use as exhibits in the trial of any case that may arise under the Act based on the sample, a part of the sample, if any remains available, shall be provided for analysis, upon written request, by any person named on the label of the article, or the owner thereof, or the attorney or agent of such person or owner, except when:

(1) After collection, the sample or remaining part thereof has become decomposed or otherwise unfit for analysis, or
(2) The request is not made within a reasonable time before the trial of any case under the Act, based on the sample, to which such person or owner is a party.

The person, owner, attorney, or agent who requests the part of sample shall specify the amount desired. A request from an owner shall be accompanied by a showing of ownership, and a request from an attorney or agent by a showing of authority from such person or owner to receive the part of sample. When two or more requests for parts of the same sample are received the requests shall be complied with in the order in which they were received so long as any part of the sample remains available therefor.

(d) When an official sample of a food, drug, or cosmetic is the basis of a notice given under section 305 of the Act, or of a case under the Act, and the person to whom the notice was given, or any person who is a party to the case, has no right under paragraph (c) of this section to a part of the sample, such person or his attorney or agent may obtain a part of the sample upon request accompanied by a written waiver of right under such paragraph (c) from each person named on the label of the article and owner thereof, who has not exercised his right under such paragraph (c). The operation of this paragraph shall be subject to the exceptions, terms, and conditions prescribed in paragraph (c) of this section.

(e) The Food and Drug Administration is authorized to destroy:

(1) Any official sample when it determines that no analysis of such sample will be made;
(2) Any official sample or part thereof when it determines that no notice under section 305 of the Act, and no case under the Act, is or will be based on such sample;
(3) Any official sample or part thereof when the sample was the basis of a notice under section 305 of the Act, and when, after opportunity for presentation of views following such notice, it determines that no other such notice, and no case under the Act, is or will be based on such sample;
(4) Any official sample or part thereof when the sample was the basis of a case under the Act which has gone to final judgment, and when it determines that no other such case is or will be based on such sample;
(5) Any official sample or part thereof if the article is perishable;
(6) Any official sample or part thereof when, after collection, such sample or part has become decomposed or otherwise unfit for analysis;
(7) That part of any official sample which is in excess of three times the quantity it estimates to be sufficient for analysis.

[Sec. 702] (c) For purposes of enforcement of this Act, records of any department or independent establishment in the executive branch of the Government shall be open to inspection by any official of the Federal Security Agency duly authorized by the Administrator to make such inspection.

SEA-FOOD INSPECTION

SEC. 702 a.[9] The Federal Security Administrator, upon application of any packer of any sea food for shipment or sale within the jurisdiction of this Act, may, at his discretion, designate inspectors to examine and inspect such food and the production, packing, and labeling thereof. If on such examination and inspection compliance is found with the provisions of this Act and regulations [10] promulgated thereunder, the applicant shall be authorized or required to mark the food as provided by regulation to show such compliance. Services under this section shall be rendered only upon payment by the applicant of fees fixed by regulation in such amounts as may be necessary to provide, equip, and maintain an adequate and efficient inspection service. Receipts from such fees shall be covered into the Treasury and shall be available to the Federal Security Administrator for expenditures incurred in carrying out the purposes of this section, including expenditures for salaries of additional inspectors when necessary to supplement the number of inspectors for whose salaries Congress has appropriated. The Administrator is hereby authorized to promulgate regulations governing the sanitary and other conditions under which the service herein provided shall be granted and maintained and for otherwise carrying out the purposes of this section. Any person who forges, counterfeits, simulates, or falsely represents, or without proper authority uses any mark, stamp, tag, label, or other identification devices authorized or required by the provisions of this section or regulations thereunder, shall be guilty of a misdemeanor, and shall on conviction thereof be subject to imprisonment for not more than one year or a fine of not less than $1,000 nor more than $5,000 or both such imprisonment and fine.

RECORDS OF INTERSTATE SHIPMENT

SEC. 703. For the purpose of enforcing the provisions of this Act, carriers engaged in interstate commerce, and persons receiving food, drugs, devices, or cosmetics in interstate commerce or holding such articles so received, shall, upon the request of an officer or employee duly designated by the Administrator, permit such officer or employee, at reasonable times, to have access to and to copy all records showing the movement in interstate commerce of any food, drug, device, or cosmetic, or the holding thereof during or after such movement, and the quantity, shipper, and consignee thereof; and it shall be unlawful for any such carrier or person to fail to permit such access to and copying of any such record so requested when such request is accompanied by a statement in writing specifying the nature or kind of food, drug, device, or cosmetic to which such request relates: *Provided*, That evidence obtained under this section shall not be used in a criminal prosecution of the person from whom obtained: *Provided further*, That carriers shall not be subject to the other pro-

[9] Sec. 902 (a) provides that the amendment to the Food and Drugs Act, section 10A, shall remain in force and effect and be applicable to the provisions of this Act. The Labor-Federal Security Appropriation Act of July 12, 1943 (ch. 221, title II, § 1, 57 Stat. 500) renumbered this section as 702A of the Federal Food, Drug, and Cosmetic Act. Title 21 U. S. C., 1946 ed., codifies this section as 372 a.

[10] 13 F. R. 6623.

visions of this Act by reason of their receipt, carriage, holding, or delivery of food, drugs, devices, or cosmetics in the usual course of business as carriers.

FACTORY INSPECTION

SEC. 704. For purposes of enforcement of this Act, officers or employees duly designated by the Administrator, after first making request and obtaining permission of the owner, operator, or custodian thereof, are authorized (1) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or are held after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, or cosmetics in interstate commerce; and (2) to inspect, at reasonable times, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein.

PUBLICITY

SEC. 705. (a) The Administrator shall cause to be published from time to time reports summarizing all judgments, decrees, and court orders which have been rendered under this Act, including the nature of the charge and the disposition thereof.

(b) The Administrator may also cause to be disseminated information regarding food, drugs, devices, or cosmetics in situations involving, in the opinion of the Administrator, imminent danger to health or gross deception of the consumer. Nothing in this section shall be construed to prohibit the Administrator from collecting, reporting, and illustrating the results of the investigations of the Agency.

COST OF CERTIFICATION OF COAL-TAR COLORS

SEC. 706. The admitting to listing and certification of coal-tar colors, in accordance with regulations [4] prescribed under this Act, shall be performed only upon payment of such fees, which shall be specified in such regulations, as may be necessary to provide, maintain, and equip an adequate service for such purposes.

CHAPTER VIII—IMPORTS AND EXPORTS

SEC. 801. (a) The Secretary of the Treasury shall deliver to the Federal Security Administrator, upon his request, samples of food, drugs, devices, and cosmetics which are being imported or offered for import into the United States, giving notice thereof to the owner or consignee, who may appear before the Federal Security Administrator and have the right to introduce testimony. If it appears from the examination of such samples or otherwise that (1) such article has been manufactured, processed, or packed under insanitary conditions, or (2) such article is forbidden or restricted in sale in the country in which it was produced or from which it was exported, or (3) such

[4] Service and Regulatory Announcements, Food, Drug, and Cosmetic No. 3.

article is adulterated, misbranded, or in violation of section 505, then such article shall be refused admission. This paragraph shall not be construed to prohibit the admission of narcotic drugs the importation of which is permitted under section 2 of the Act of May 26, 1922, as amended (U. S. C., 1934 edition, title 21, sec. 173).

(b) The Secretary of the Treasury shall refuse delivery to the consignee and shall cause the destruction of any such article refused admission, unless such article is exported by the consignee within three months from the date of notice of such refusal, under such regulations as the Secretary of the Treasury may prescribe: *Provided*, That the Secretary of the Treasury may deliver to the consignee any such article pending examination and decision in the matter on execution of a bond as liquidated damages for the amount of the full invoice value thereof together with the duty thereon and on refusing for any cause to return such article or any part thereof to the custody of the Secretary of the Treasury when demanded for the purpose of excluding it from the country or for any other purpose, such consignee shall forfeit the full amount of the bond as liquidated damages.

[§ 1.302] (a) *Bonds—delivery—sampling.* No food, drug, device, or cosmetic shall be delivered to the consignee prior to report of examination of such article, or prior to the stamping of the invoice as prescribed by paragraph (b) of this section showing that no sample is desired, except upon the execution on the appropriate form of a customs single-entry or term bond, containing a condition for the redelivery of the merchandise, or any part thereof, upon demand of the collector of customs at any time, in such amount as is prescribed for such bonds in the customs regulations in force on the date of entry. The bond shall be filed with the collector of customs, who, in case of default, shall take appropriate action to effect the collection of liquidated damages provided for in the bond.

(b) As soon as the importer makes entry of an article, the invoice covering it and the package of it designated by the collector of customs for examination shall be made available, with the least possible delay, for inspection by a representative of the district. When a sample is desired the representative shall request the collector of customs or the appropriate customs officer therefor, indicating the size of the sample. When no sample is desired the invoice shall be stamped by the representative "No sample desired. Food and Drug Administration, Federal Security Agency, per (initials of the representative)."

(c) (1) At ports of entry where there is no laboratory of the Food and Drug Administration the collector of customs or appropriate customs officer shall, on the day of receipt of the first notice, by invoice or entry, of an expected shipment of article subject to the Act, notify the chief of district, within whose territory the port is located, of the expected shipment.

(2) If no sample is desired, the chief of district, on the day he receives the notice, shall advise the collector of customs or appropriate customs officer by mail to that effect. Such advice shall be equivalent to stamping invoices at ports where districts are located with the statement prescribed in paragraph (b) of this section.

(3) If a sample is desired, the chief of district shall immediately request the collector of customs or appropriate customs officer to forward it and indicate the size of sample.

(4) Upon receipt of such request the collector of customs or appropriate customs officer shall forward the sample without delay, together with a description of the shipment.

(5) When samples will be desired from each shipment of a particular article or when samples will not be desired, the chief of district shall furnish, at least every 6 months, to collectors of customs or appropriate customs officers within the district territory, a list of such articles and on the list of articles of which samples will be desired, shall indicate the size of sample for each such article. Upon the arrival of shipments of articles appearing on the list of samples which will be desired, the collectors of customs or appropriate customs officers shall

send such samples to the district without delay, together with a description of the shipments. The list of articles, samples of which will not be requested, shall be treated as the equivalent of paragraph (b) of this section and the invoices of such articles shall be handled accordingly.

(6) In all particulars the procedure shall be the same at non-laboratory ports as at laboratory ports except that the time consumed in delivery by mail of the notice of hearing shall be allowed for.

[§ 1.303] *Jurisdiction.* (a) Whether or not an article is in compliance with or in violation of the provisions of section 801 of the Act is to be determined by the officers of the districts of the Food and Drug Administration.

(b) The detention, exportation, and destruction of merchandise shall be accomplished under customs supervision. At laboratory ports customs officers and officers of the Food and Drug Administration may alternately, in accordance with local agreement, perform duties, or supervise operations, under §§ 1.302–1.312, which are not specifically assigned to either service, consideration being given to local conditions and personnel.

(c) At non-laboratory ports the collector of customs or appropriate customs officer shall carry out the necessary operations on receipt of the necessary information from the chief of district of the Food and Drug Administration of the appropriate laboratory port.

[§ 1.304] *Notices required under Sec. 801 of the Act.* All notices required by regulation under section 801 of the Act to be given to the owner or consignee of an article offered for import shall be deemed to have been duly and effectively given if given to the importer of record of such article.

[§ 1.305] *Notice of sampling.* (a) A notice to an owner or consignee that a sample of an article has been requested by the Federal Security Administrator shall be in writing and shall be mailed by the collector of customs or appropriate customs officer to such owner or consignee, or such notice may be given by a suitable bulletin notice posted in the custom house listing all invoices of articles from which samples will be taken and posted in the custom house not later than 1 day after the day the decision is reached to take samples from such articles. Such bulletin notice shall remain posted for 1 week.

(b) The notice to an owner or consignee that a sample of an article has been requested by the Federal Security Administrator shall likewise state that such article must be held intact until released.

[§ 1.306] *Release; No violation detected.* If it does not appear from the examination of the sample or otherwise that an article is adulterated, misbranded or in any other respect subject to prohibitions of the Act, the chief of district of the Food and Drug Administration shall give written notice of release to the owner or consignee of such article and a copy thereof shall be sent to the collector of customs or appropriate customs officer.

[§ 1.307] *Procedure when violation is alleged.* (a) If the result of the examination of the sample or other evidence indicates that an article is adulterated, misbranded, or otherwise subject to the prohibitions of the Act, the chief of district of the Food and Drug Administration shall give written notice thereof to the owner or consignee of such article and a copy thereof shall be sent to the collector of customs or appropriate customs officer. Such notice shall allege the respects in which such article appears to be adulterated, misbranded, or otherwise subject to the prohibitions of the Act, and shall set a time and place for such owner or consignee to appear and introduce testimony.

(b) Such testimony shall be confined to matters relevant to the alleged adulteration, misbranding or other condition subject to the prohibitions of the Act, and may be introduced by letter or in person by such owner or consignee, or by a representative chosen by him for the purpose.

(c) Upon request, seasonably made, by such owner, consignee, or representative, such time may be changed if the request states reasonable grounds therefor and is made on or prior to the date for the hearing. Such request shall be addressed to the chief of district of the Food and Drug Administration which issued the notice.

[§ 1.308] *Procedure after hearing; release or rejection and notice.* (a) After the owner or consignee of an article appears, produces testimony, or is given reasonable opportunity therefor, as provided by § 1.307 (b), the chief of district of the Food and Drug Administration, over the signature of the collector of customs or authorized stamped facsimile thereof, shall notify such owner or consignee in writing that such article is released so far as the Act is concerned, and send a carbon copy of the notice to the collector of customs or appropriate customs officer, or so notify such owner or consignee, that it appears from such examination that such article does not conform with the provisions of the Act, and that it is to be refused admission, stating the reason therefor in such notice and send a carbon copy of the notice to the collector of customs or appropriate customs officer.

(b) The notice of refusal of admission shall state that the article must be exported or destroyed under customs supervision within 3 months of the date thereof, as provided by law. The owner or consignee (or importer of record in case notice has been sent to him) shall return the notice to the collector of customs or appropriate customs officer with the information required by the form filled in and properly certified. The copy of the notice sent to the collector of customs by the chief of district, when action is completed, shall then be returned to the chief of district with notation thereon of the action taken. The exportation of articles refused admission under the Act or the regulations thereunder shall be in accordance with the procedure set forth in the applicable customs regulations which have been or may be prescribed by the Secretary of the Treasury.

[§ 1.309] *Relabeling or other act to bring article into compliance with the Act and notice.* (a) The owner or consignee of an article may, at the time of the hearing or within a reasonable time thereafter, request the chief of district of the Food and Drug Administration in writing to permit the relabeling or other act with respect to such article necessary to bring it into compliance with the provisions of the Act, or to render it not a food, drug, device, or cosmetic within the meaning of the definitions of such articles in section 201 (f), (g), (h), and (i) of the Act. Such request shall propose the labeling to be used and any other act to be done for such purpose, and shall specify the time and place where such proposed labeling or other act is to be done.

(b) Unless such relabeling or other act with respect to such article is prohibited by paragraph (c) of this section, the chief of district of the Food and Drug Administration, over the signature of the collector of customs or authorized stamped facsimile thereof, will give such owner or consignee written notice that such relabeling or other act will be permitted, and send a carbon copy of the notice to the collector of customs.

Such notice shall specify all conditions which must be fulfilled within 3 months of the date of the notice in order to bring such article into compliance with the provisions of the Act including the destruction, under customs supervision, of all rejected material, or to render it not a food, drug, device, or cosmetic within the meaning of the definitions of such articles in section 201 (f), (g), (h), and (i) of the Act, and to bring the performance thereof within the provisions of the bond covering the merchandise.

In addition, the notice shall also indicate the officer who shall be notified by the owner or consignee (or the importer of record if notice has been sent to him) when the operations have been completed and the article is ready for inspection. If such conditions are fulfilled within 3 months of the date of the notice specified by this paragraph, such article will be released, and notice thereof given to the owner or consignee. A carbon copy of the notice shall be sent to the collector of customs.

(c) When it appears that the labeling constitutes a flagrant or intentional misbranding, or that the condition of the article is such as to indicate deliberate adulteration, or the owner or consignee thereof was informed with respect to any violation prior to the date of export, or that a public notice had been issued by the Federal Security Administrator to the effect that, after a date prior to such date of export, such relabeling or other act with respect to such article would not be permitted, then the provisions of the preceding paragraphs shall not apply and the article must be destroyed or exported under customs supervision.

(d) When relabeling or other act with respect to such article is to be allowed under the provision of paragraph (b) of this section, the owner or consignee (or importer of record if the notice has been sent to him) shall return the notice to the collector of customs, or the appropriate customs officer, or chief of district

designated thereon, with the certificate on the notice filled out stating that he has performed the prescribed operations, that the rejected portion required to be held for destruction is so held and is ready for destruction under customs supervision, that the article, including such rejected portion, is ready for inspection, naming the place where such article and such portion are held.

(e) The officer so notified shall deliver the notice to the representative of the Food and Drug Administration or to the appropriate customs officer who is to make the inspection. After inspection the representative shall write a report thereof on the back of the notice and send it to the collector of customs, or the appropriate customs officer, or chief of district, as the case may be, from whom he received the notice.

[§ 1.310] *Release of detained goods which have been reconditioned.*

(a) (1) When the operations to be performed are under the entire supervision of the chief of the district, and these operations have been effectively and completely performed and all of the conditions imposed have been fulfilled within the time prescribed therefor, he shall give notice to the importer that the article is released insofar as the provisions of the Act relate thereto and shall send a copy thereof to the collector of customs or the appropriate customs officer; but if the operations have not been effectively and completely performed and all of the conditions imposed have not been fulfilled within the time prescribed therefor, and the article is to be exported or destroyed, the chief of station, over the signature of the collector of customs, or authorized stamped facsimile thereof, shall immediately give notice of refusal of admission to the importer and shall send a carbon thereof to the collector of customs or the appropriate customs officer. Such notice shall show that the article must be exported or destroyed, under customs supervision, within 3 months from the date of notice, as required by law.

(2) When, however, the operations to be performed are under the supervision of the chief of district and the destruction of a rejected portion of the article under customs supervision is a condition of the release, the chief of district shall give notice to the collector of customs or the appropriate customs officer that the portion which has been brought into compliance with the act is ready for release after destruction of the rejected portion has been accomplished, under customs supervision, and transmit to him the notice received from the importer with the form thereon properly filled in showing that the rejected portion is ready for destruction. The collector of customs or the appropriate customs officer, with the least possible delay, shall supervise the destruction of the rejected portion. Within 1 day after such destruction the collector of customs or the appropriate customs officer shall return such notice to the chief of district after having noted thereon that the destruction has been accomplished. Within 1 day after the receipt of such notice the chief of district shall send notice of release of the article to the importer and a carbon copy thereof to the collector of customs or appropriate customs officer.

(b) When all the operations to be performed are under customs supervision, and these operations have been effectively and completely performed within the time prescribed therefor, the collector of customs or the appropriate customs officer shall give the notice of release of the article to the owner or consignee and shall send a carbon copy thereof to the chief of district. If the conditions imposed include destruction of the rejected portion of the article, no release of the article shall be given until the rejected portion has been destroyed under customs supervision. If, however, operations have not been effectively and completely performed within the time prescribed therefor, the collector of customs or appropriate customs officer shall give notice to the owner or consignee that the article shall be exported or destroyed within 3 months from the date of the notice and shall send a copy thereof to the chief of district.

(c) The privilege of relabeling or other operation to bring an article into compliance with the Act shall be allowed only when the owner or consignee agrees to hold the article at a stated place and to maintain conditions at all times which will preserve the identity of the article and prevent its loss through mixture with other articles or otherwise. The owner or consignee shall furnish evidence satisfactory to the chief of district or collector of customs or appropriate customs officer by affidavit or otherwise as to the identity of any article which has been subject to such operations.

(d) When the collector of customs or the appropriate customs officer has taken final action with respect to an article which has been refused admission, or with respect to which relabeling or other operations have been permitted under his supervision he shall give notice thereof to the chief of district, showing the date of release or destruction, or the date of exportation and the country to which the article is exported, as the case may be.

(e) The chief of district may require that the owner or consignee submit affidavits executed before a Notary Public or other officer authorized to administer oaths generally, showing to the satisfaction of the chief of district the use to which such article has been put.

(f) Inspection of articles under the Act involving relabeling and other operations to bring them into compliance with the Act when no representative of the district is available therefor, and inspection of articles to be exported or destroyed, in whole or in part, shall be performed by collectors of customs or the appropriate customs officers.

(g) Collectors of customs and chiefs of districts shall make joint arrangement for the apportionment of inspection duties between them, due regard being given to local conditions. Whenever feasible representatives of districts at laboratory ports shall inspect articles which have been relabeled or subjected to other operations to bring them in compliance with the Act. At non-laboratory ports relabeling and other operations will be under the supervision of the collector of customs or the appropriate customs officer.

[§ 1.311] *Disposal in violation of the Act, regulations or bond.* (a) If a customs officer who has supervision over the disposal of an article acquires evidence tending to show that the disposal was in violation of the Act or of §§ 1.309 and 1.310 or of the terms of the bond, the collector of customs or appropriate customs officer shall immediately send such evidence in detail, to the chief of district. The chief of district shall send to the collector of customs or the appropriate customs officer a statement giving a summary of all the facts and any additional evidence which he may have tending to show the importers' liability under the bond.

(b) If the chief of the district has supervision over the disposal of an article and acquires evidence that the disposal was in violation of the Act or this part, or of the terms of the bond, he shall immediately send to the collector of customs or the appropriate customs officer a statement giving a summary of all the facts and any evidence he may have tending to show the importers' liability under the bond.

(c) The collector of customs or the appropriate customs officer, within 3 days of receipt of the statement and evidence, shall notify the owner or consignee that the article must be returned to customs custody. If the article is not returned to customs custody within 30 days from the date of the notice, action shall be taken immediately to enforce the terms of the bond unless, in the meantime, the owner or consignee shall file with the collector of customs or the appropriate customs officer an application for cancellation of the liability incurred under the bond upon the payment as liquidated damages of a lesser amount than the full amount of the liquidated damages incurred, or upon the basis of such other terms and conditions as may be deemed sufficient. The application shall contain a full statement of the reasons for the requested cancellation and shall be in triplicate and under oath.

(d) Upon the receipt of an application for relief as provided for in paragraph (c) of this section, the collector of customs may cancel the liability for liquidated damages incurred under the bond upon the payment of a lesser amount or upon such other terms and conditions as shall be deemed appropriate under the law and in view of the circumstances, but the collector shall not act under the section in any case unless the chief of district having jurisdiction at the port of entry is in full agreement with the action.

(e) All notices required by regulation under section 801 of the Act to be given to the owner or consignee of an article offered for import shall be deemed to have been duly and effectively given if given to the importer of record of such article.

[§ 1.312] *Article suitable only for technical or restricted use, denaturing.* (a) A food, drug, or cosmetic which is adulterated or misbranded within the meaning of this Act and which is offered for import for industrial purposes must be denatured and the invoice thereof must bear a statement showing that the article is to be used for industrial purposes.

Where, however, it is impracticable to denature such article it may be permitted entry, *Provided:*

(1) It is plainly and conspicuously labeled, in the case of food, "inedible," and, in the case of drugs, "not for medicinal use."
(2) At the time of entry the owner or ultimate consignee submits a statement in writing that the article will not be used as a food, drug, or cosmetic.
(3) At the time of entry the owner or ultimate consignee submits a statement that the article will be used in a certain suitable manner by a certain named party or parties.
(4) At the time of entry the owner or ultimate consignee agrees to furnish satisfactory proof as to the actual use of the article and the name or names of the parties who use it.

The liability under the bond given at the time of entry will not be regarded as having been satisfied until such evidence of satisfactory disposition shall have been received by the collector of customs.

(b) A food, drug, or cosmetic having but a restricted legitimate use and of such character that it cannot legally be distributed for unrestricted general use, e. g., pharmacopoeial crude drugs deficient in active principle and certain substitutes for pharmacopoeial crude drugs, may be allowed entry if properly labeled, provided suitable evidence be furnished by affidavit or otherwise that it will be used by a designated party or parties for manufacture into articles in which it may be legitimately employed. The liability under the bond given at the time of entry will not be regarded as having been satisfied until proof of satisfactory use of the product shall have been received by the collector of customs.

[Sec. 801]. (c) All charges for storage, cartage, and labor on any article which is refused admission or delivery shall be paid by the owner or consignee and in default of such payment shall constitute a lien against any future importations made by such owner or consignee.

(d) A food, drug, device, or cosmetic intended for export shall not be deemed to be adulterated or misbranded under this Act if it (1) accords to the specifications of the foreign purchaser, (2) is not in conflict with the laws of the country to which it is intended for export, and (3) is labeled on the outside of the shipping package to show that it is intended for export. But if such article is sold or offered for sale in domestic commerce, this subsection shall not exempt it from any of the provisions of this Act.

CHAPTER IX--MISCELLANEOUS

SEPARABILITY CLAUSE

Sec. 901. If any provision of this Act is declared unconstitutional, or the applicability thereof to any person or circumstances is held invalid, the constitutionality of the remainder of the Act and the applicability thereof to other persons and circumstances shall not be affected thereby.

EFFECTIVE DATE AND REPEALS

Sec. 902. (a) This Act shall take effect twelve months after the date of its enactment.[11] The Federal Food and Drugs Act of June 30, 1906, as amended (U. S. C., 1934 ed., title 21, secs. 1–15), shall remain in force until such effective date, and, except as otherwise provided in this subsection, is hereby repealed effective upon such date: *Provided*, That the provisions of section 701 shall become effective on the enactment of this Act, and thereafter the Secretary [of

[11] The Act of June 23, 1939 (see p. 57), temporarily postponed the operation of certain provisions until January 1, 1940, and July 1, 1940.

Agriculture] is authorized hereby to (1) conduct hearings and to promulgate regulations which shall become effective on or after the effective date of this Act as the Secretary [of Agriculture] shall direct, and (2) designate prior to the effective date of this Act food having common or usual names and exempt such food from the requirements of clause (2) of section 403 (i) for a reasonable time to permit the formulation, promulgation, and effective application of definitions and standards of identity therefor as provided by section 401: *Provided further*, That sections 502 (j), 505, and 601 (a), and all other provisions of this Act to the extent that they may relate to the enforcement of such sections, shall take effect on the date of the enactment of this Act, except that in the case of a cosmetic to which the proviso of section 601 (a) relates, such cosmetic shall not, prior to the ninetieth day after such date of enactment, be deemed adulterated by reason of the failure of its label to bear the legend prescribed in such proviso: *Provided further*, That the Act of March 4, 1923 [12] (U. S. C., 1934 ed., title 21, sec. 6; 42 Stat. 1500, ch. 268), defining butter and providing a standard therefor; the Act of July 24, 1919 [13] (U. S. C., 1934 ed., title 21, sec. 10; 41 Stat. 271, ch. 26), defining wrapped meats as in package form; and the amendment to the Food and Drugs Act, section 10A, approved August 27, 1935 [14] (U. S. C., 1934 ed., Sup. III, title 21, sec. 14a [49 Stat. 871, ch. 739]), shall remain in force and effect and be applicable to the provisions of this Act.

(b) Meats and meat food products shall be exempt from the provisions of this Act to the extent of the application or the extension thereto of the Meat Inspection Act, approved March 4, 1907, as amended (U. S. C., 1934 ed., title 21, secs. 71–91; 34 Stat. 1260 *et seq.*).

(c) Nothing contained in this Act shall be construed as in any way affecting, modifying, repealing, or superseding the provisions of the virus, serum, and toxin Act of July 1, 1902 (U. S. C., 1934 ed., title 42, chap. 4); the Filled Cheese Act of June 6, 1896 (U. S. C., 1934 ed., title 26, ch. 10), the Filled Milk Act of March 4, 1923 (U. S. C., 1934 ed., title 21, ch. 3, secs. 61–63); or the Import Milk Act of February 15, 1927 (U. S. C. 1934 ed., title 21, ch. 4, secs. 141–149.).

(d) In order to carry out the provisions of this Act which take effect prior to the repeal of the Food and Drugs Act of June 30, 1906, as amended, appropriations available for the enforcement of such Act of June 30, 1906, are also authorized to be made available to carry out such provisions.

(Approved June 25, 1938.)

[12] That for the purposes of the Food and Drug Act of June 30, 1906 (Thirty-fourth Statutes at Large, page 768), "butter" shall be understood to mean the food product usually known as butter, and which is made exclusively from milk or cream, or both, with or without common salt, and with or without additional coloring matter, and containing not less than 80 percentum by weight of milk fat, all tolerances having been allowed for.

[13] That the word "package" where it occurs the second and last time in the Act entitled "An act to amend section 8 of an act entitled, 'An act for preventing the manufacture, sale, or transportation of adulterated or misbranded or poisonous deleterious foods, drugs, medicines, and liquors, and for regulating traffic therein, and for other purposes," approved March 3, 1913, shall include and shall be construed to include wrapped meats inclosed in papers or other materials as prepared by the manufacturers thereof for sale.

[14] See footnote 9, p. 48.

PUBLIC—NO. 151—76TH CONGRESS
AN ACT

To provide for temporary postponement of the operations of certain provisions of the Federal Food, Drug, and Cosmetic Act.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That (a) the effective date of the following provisions of the Federal Food, Drug, and Cosmetic Act is hereby postponed until January 1, 1940: Sections 402 (c); 403 (e) (1); 403 (g), (h), (i), (j), and (k); 501 (a) (4); 502 (b), (d), (e), (f), (g), and (h); 601 (e); and 602 (b).

(b) The Secretary of Agriculture shall promulgate regulations further postponing to July 1, 1940, the effective date of the provisions of sections 403 (e) (1); 403 (g), (h), (i), (j), and (k); 502 (b), (d), (e), (f), (g), and (h), and 602 (b) of such Act with respect to lithographed labeling which was manufactured prior to February 1, 1939, and to containers bearing labeling which, prior to February 1, 1939, was lithographed, etched, stamped, pressed, printed, fused or blown on or in such containers, where compliance with such provisions would be unduly burdensome by reason of causing the loss of valuable stocks of such labeling or containers, and where such postponement would not prevent the public interest being adequately served: *Provided,* That in no case shall such regulations apply to labeling which would not have complied with the requirements of the Food and Drugs Act of June 30, 1906, as amended.

SEC. 2 (a) The provisions of section 8, paragraph fifth, under the heading "In the case of food:", of the Food and Drugs Act of June 30, 1906, as amended, and regulations promulgated thereunder, and all other provisions of such Act to the extent that they may relate to the enforcement of such section 8 and of such regulations, shall remain in force until January 1, 1940.

(b) The provisions of such Act of June 30, 1906, as amended, to the extent that they impose, or authorize the imposition of, any requirement imposed by section 403 (k) of the Federal Food, Drug, and Cosmetic Act, shall remain in force until January 1, 1940.

(c) Notwithstanding the provisions of section 1 of this Act, such section shall not apply—

(1) to the provisions of section 502 (d) and (e) of the Federal Food, Drug, and Cosmetic Act, insofar as such provisions relate to any substance named in section 8, paragraph second, under the heading "In the case of drugs:", of the Food and Drugs Act of June 30, 1906, as amended, or a derivative of any such substance; or

(2) to the provisions of section 502 (b), (d), (e), (f), (g), and (h) of the Federal Food, Drug, and Cosmetic Act, insofar as such provisions relate to drugs to which section 505 of such Act applies.

SEC. 3. Section 502 (d) of the Federal Food, Drug, and Cosmetic Act is hereby amended by striking out the words "name, quantity, and percentage" where they appear therein and substituting in lieu thereof "name, and quantity or proportion".

Approved June 23, 1939.

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